An Uncertain Business

Industry Responses to the Regulation of Nanotechnologies

Pelle Moos

Thesis submitted for assessment with a view to
obtaining the degree of Doctor of Political and Social Sciences
of the European University Institute

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European University Institute
Department of Political and Social Sciences

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ABSTRACT

This thesis is an account of international efforts to assess and control the possible human health and environmental effects of nanotechnologies. I show how the desire to reap the benefits of nanotechnologies has led decision-makers in America and Europe to adopt very similar policy strategies. While political reactions thus are largely comparable, industry responses however differ remarkably. The diverging industry reactions to comparable state policies invite a closer inspection of the institutional drivers of business behavior in regulatory politics. I trace the roots of the varied business responses through two case studies that explore how the institutions and processes of national chemical control regimes link to the strategic risk-benefit calculations of companies. I examine the policies developed to regulate the risks of nanomaterials in Britain, Denmark, Germany and the United States and compare the role of industry in the four countries' regulatory processes.

I argue that the capacity of state bureaucrats to credibly commit to regulatory outcomes shapes the political behavior of business. In areas of high scientific and technical uncertainty, such as nanotechnologies, new information can exercise significant influence on regulatory agendas, priorities and policies. This can work in industry's favor, if disclosing information succeeds in convincing state bureaucrats to make decisions that benefits industry. Companies will however only volunteer information about their operations if they are confident that it will not be used to the detriment of their interests. I demonstrate how concentration of regulatory powers in executive bureaucracies and deliberative institutions structure business expectations about the probable behavior of state authorities, and how such institutions can convince companies to entrust state bureaucrats with sensitive information. The thesis in short speaks to the significant business influence over the outcome of regulatory politics that flows from the power to disclose, bias and withhold information from state authorities.

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Preface

This thesis began with a familiar question: why do industries self-regulate? I was led to this question in part from a curiosity of international efforts to regulate nanotechnologies and the observation that reactions of industries in America and Europe differed: whereas companies in Britain and Germany have embraced self-governance in the form of codes of responsible conduct, comparable initiatives are conspicuously absent in the United States and Denmark. A commonly held view among political scientists understands self-regulation as a strategy crafted to starve off a threat of state intervention in the affairs of an industry. The pervasive risk uncertainties associated with nanotechnologies are indeed widely recognized as demanding a regulatory response to guarantee that possible hazards are effectively controlled. Nanobusinesses obviously have much riding on the nature of this response. Statutory regulations could increase business costs, erect barriers to market entry, result in lower or changing patterns of innovation and so on. And, as could be expected, corporate representatives and industry insiders have undeniably been quick to warn of the dire, if not catastrophic consequences of 'premature' regulations. The fervor of the nanotech debate in short suggests that British and German companies self-regulated to thwart a legislative response.

In the course of researching the evolving regulatory process, it however became abundantly clear that governments in America and Europe wanted much the same things. In hindsight, this is not surprising. Having staked enormous financial and political resources on nanoscience and technology, decision-makers on both sides of the Atlantic share an obvious ambition of 'getting it right'. The desire to reap the benefits of nanotechnologies, while avoiding the pitfalls, has in turn led governments to adopt very similar policy strategies. Schematically summarized, these include formal strategies or policy statements, combined with attempts to expand the knowledge base on potential risks, ultimately leading not to new legislation, but indirect regulation of nanotechnologies through existing legal frameworks. This created a puzzle: if not born of a desire to preempt new legislative controls – which were never seriously considered in either America or

Europe – how can we account for the codes of responsible conduct launched by companies in Britain and Germany? Why were no similar initiatives undertaken in the United States and Denmark?

My initial interest in self-regulation in turn led to a closer inspection of the regulatory process. Nanotechnologies have created intricate difficulties for regulatory authorities to not only gauge the need for immediate action, but also to develop appropriate risk assessment and management instruments. Governments have consequently devoted considerable resources to shore up the knowledge base, combined with appeals for cooperation among all relevant stakeholders and an emphasis on the strategic value of partnerships with industry. The regulatory process has in other words presented industry with other opportunities and predicaments than a mere desire to forestall statutory regulations. With state authorities scrambling at the complexities of scientific uncertainty, new information can exercise a significant influence on regulatory agendas, priorities and policies. We might thus have expected industries to jump on the opportunity to mold regulatory outcomes to suit their needs and interests. Yet, while governmental preferences and strategies in the four countries were largely similar, industries have responded remarkably different: disengagement from regulators in the United States, acquiescence and adaptation in Denmark, and active participation and cooperation with governmental officials in Britain and Germany. The thesis therefore ultimately became an inquiry into the drivers of business behavior in regulatory politics. What follows then is an account of international efforts to assess and control the human health and environmental risks of nanotechnologies and the significant, yet often surreptitious business influence that flows from the power to disclose, bias and withhold information from state authorities.

Throughout the course of this doctoral project, I have relied on the support and invaluable advice of a number of individuals. First and foremost, I wish to thank my supervisors, Pepper D. Culpepper and Adrienne Héritier for their insightful and stimulating guidance. In Pepper and Adrienne I found engaged readers and a source of extremely competent and above all always constructive criticism. Needless to say this dissertation would have been vastly different without their barrage of penetrating questions, constant probing for inconsistencies and gentle nudges at critical junctures. I acknowledge both with gratitude. I should also like to thank the members of my jury, who kindly agreed to consider my work and discuss its results. I am indebted to Alina Maria Vlad and Valentina Zuri in whose capable hands I have confidently left the task of organizing my defense. I owe a particular debt of gratitude to the many knowledgeable business people, bureaucrats and representatives in Europe and the United States, who generously took

the time to walk me through the promises and pitfalls of nanotechnologies. Anonymity was a guarantee for their candor in explaining the complex and intractable difficulties of designing appropriate control policies and I respect it throughout. But the thesis could not have been written without their help.

During my four years in Florence, I have benefitted tremendously from the vibrant and unique intellectual environment at the EUI. I have enjoyed pleasant and inspiring conversations with a great number of researchers and scholars – visiting as well as resident. Among those who deserve special thanks for their advice and inputs are Johan Christensen, who – on more occasion than I care to think about – patiently listened to my attempts to make sense of the business of nanotech regulation and always offered valuable suggestions in return, David Karas, Emre Bayram and Juan Mayoral for their comments and encouragements at various stages of my work, and Frédérique Roche for assuming the tedious but essential task of editing my dissertation and for her intellectual feedback when I needed it the most. The EUI staff – from the library over the administration to the bar – deserves credit for keeping the wheels running and thus enabling the writing of my dissertation. I am grateful to Gabriella Unger for her open door policy and for her affinity for us, the researchers.

Thanks also to Christian Rewitz, who gave me a basic notion of the science of the nanoscale, Simon Backovsky for his thoughts on social science inquiry, Tanja Ehnert for reminding me of the many legal niceties and nuances a company must consider when bringing a product to market, and Sarah Pelletier, who among other useful things taught me how to recall the names of all U.S. states. Special thanks are due to Peter Munk Christiansen, for lending me his wisdom, and to Anne-Stine Jørck – a true friend indeed.

I am thankful for my family and friends – particularly for their pardon of my long spells of silence as I wrestled with wrapping up my dissertation. I am especially grateful to my parents for their love, encouragements and belief in me: Knud, who took an independent interest in the regulation of nanomaterials, and Mona, whose indignation motivated my concluding thoughts on the control of chemicals hazards. The greatest debt of gratitude, however, I owe to my wife: although she – understandably – never took as keen an interest in the predicaments and aspirations of nanobusinesses as I might have desired, her interest and attention to me never faltered. More than anything, her loving company, common sense and humor have sustained me through these past four years. I am truly fortunate for the time we have and will spend together and for her never failing ability to remind me that there are larger things in life than small particles.

Abbreviations

ACC	American Chemistry Council
ACHS	Advisory Committee on Hazardous Substances
AGS	Ausschuss für Gefahrstoffe (Committee on Hazardous Substances)
AMR	Arbejdsmiljørådet (Danish Working Environment Council)
AT	Arbejdstilsynet (Danish Working Environment Authority)
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health)
BfR	Bundesinstitut für Risikobewertung (German Federal Institute for Risk Assessment)
BIS	UK Department of Business, Innovation & Skills
BMAS	Bundesministerium für Arbeit und Soziales (German Federal Ministry of Labour and Social Affairs)
BMBF	Bundesministerium für Bildung und Forschung (German Federal Ministry of Education and Research)
BMU	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (German Federal Ministry of the Environment, Nature Conservation and Nuclear Safety)
BMWi	Bundesministerium für Wirtschaft und Technologie (German Federal Ministry of Economics and Technology)
CBAN	Consultative Boards for Advancing Nanotechnology
CIA	UK Chemical Industries Association
CNT	Carbon nanotubes
DECHEMA	Gesellschaft für Chemische Technik und Biotechnologie e.V. (German Society for Chemical Engineering and Biotechnology)
Defra	UK Department for Environment, Food and Rural Affairs

DI	Dansk Industri (Confederation of Danish Industry)
ECHA	European Chemicals Agency
EPA	U.S. Environmental Protection Agency
FACA	U.S. Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
HSE	UK Health and Safety Executive
ILSI	International Life Science Institute
MST	Miljøstyrelsen (Danish Environmental Protection Agency)
NEHI	Nanotechnology Environmental and Health Implications
NFA	Det Nationale Forskningscenter for Arbejdsmiljø (National Research Centre for the Working Environment)
NIA	UK Nanotechnology Industries Association
NIOSH	U.S. National Institute for Occupational Health and Safety
NMSP	Nanoscale Material Stewardship Program
NNI	U.S. National Nanotechnology Initiative
NPPTAC	National Pollution Prevention and Toxics Advisory Committee
NRCG	Nanotechnology Research Coordination Group
NSF	Nanotechnologies Stakeholder Forum
OECD	Organisation for Economic Co-operation and Development
OIRA	U.S. Office of Information and Regulatory Affairs
OMB	U.S. Office of Management and Budget
OSHA	U.S. Occupational Safety and Health Administration
REACH	European Union Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
SNUR	Significant new use rule
SOCMA	Society of Chemical Manufacturers and Affiliates
TRGS	Technische Regeln für Gefahrstoffe (Technical Rules for Hazardous Substances)
TSCA	U.S. Toxic Substances Control Act
UBA	Umweltbundesamt (German Federal Environment Agency)
VCI	Verband der Chemischen Industrie e.V. (German Chemical Industry Association)
VRS	Voluntary Reporting Scheme
WATCH	Working Group on Action to Control Chemicals

CHAPTER ONE

The Uncertain Promise of Small Particles

We are in this awkward middle territory where we have just enough information to think there is an issue, but not enough information to really inform policymakers about what to do about it.

Kristen Kulinowski, Director of the International Council on Nanotechnology
(Quoted in Morrissey 2007)

Anyone interested in the influence of business on the policy process must therefore examine the information needed to make specific policy decisions and consider how the struggle over that information ultimately shapes the decisions that government makes.

Cary Coglianese (2007: 205)

There are fairytales about industries – that they never want to have regulations.

German official[1]

Nanotechnologies and the purposeful manipulation of matter at the atomic level are expected to be among the defining technologies of the 21st century. At the nanoscale – the size range from one to one hundred billionth of a meter – materials and particles can have markedly different properties than their larger chemical equivalents. This is both the promise of the technology and the cause of major concern over different behaviors, fates and toxicity. Debate on how to address the suspected, yet unknown risks of nanotechnologies began around the turn of the millennium and has yet to conclude. This thesis is an account of international efforts to assess and control the uncertain risks of nanomaterials over the decade from 2003 to 2013. I track the evolution of state control policies in Britain, Denmark, Germany and the United States and recount how industries in these four countries have responded to the regulatory process – and why. At the

[1] Interview, Berlin, June 22, 2012.

heart of this account then, is the nature of relations among state authorities responsible for overseeing human health and environmental safety and representatives of the chemical industry. This opening chapter is devoted to presenting the questions motivating my investigation of nanotech regulation and how I intend to answer them as well as the empirical subject of my inquiry and its theoretical ambitions. To illustrate the range of questions, concepts and quandaries with which this account wrestles, let us however first consider an example that can help ground and thus demystify what follows.

The Industrial Age left a toxic legacy. The advance of industrial civilization created a vast and ever-increasing stream of wastes, toxins and noxious substances. By the time Rachel Carson's pathbreaking bestseller *Silent Spring* hit bookstores in 1962, the chemical industry had already produced some 100 trillion pounds of toxic wastes – enough to create a highway to the moon, 100 feet wide and 10 feet deep (Montague 1992). For much of the 20th century, hazardous industrial, household and military wastes were indiscriminately flushed into the environment – unsupervised and often through illicit and clandestine methods – simply buried, abandoned and forgotten (Collins 2010: 84ff.). Festering beneath the surface, this insidious legacy slowly invaded its surroundings, seeping into aquifers, contaminating food supplies, poisoning fragile ecosystems and percolating through residential areas – and in short order a host of human tragedies and toxic calamities ensued. The scale of soil and groundwater contamination is daunting and the complexities and costs of remediation are just as staggering. In the United States alone, some 150,000 contaminated sites have been identified and an additional 200,000 sites are expected to require cleanup over the next 30 years (EPA 2004). Available remediation techniques are unfortunately slow, costly, inefficient, and resource-consuming – and many result in highly contaminated wastes that then themselves have to be disposed. At US$ 100 per ton of contaminated soil excavated, reclaimed and treated – a common benchmark – the aggregated financial burden for site cleanup is truly colossal (Zhang 2003: 323).

Advances in chemistry and material science now promises novel solutions to old problems. Nanoscale iron particles represent a new generation of remedial techniques that could provide cost-effective and extremely versatile tools for some of the most vexing cleanup problems. Owing to their diminutive size, nanoparticles can increase chemical catalysis and reaction rates, pervade very small spaces in the subsurface and remain suspended in groundwater, allowing them to achieve wider distribution than their macro-scale equivalents. Nano-remedial methods are expected to offer efficient and flexible solutions to contaminants that are known to be persistent in the environment, recalcitrant to many treatments and highly toxic to human health (EPA 2007; Karn, Kuiken and Otto 2009). Beyond its significant environmental promise, nano-remediation is

also attractive from an economic perspective: developing cost-effective treatment technologies could save billions of dollars in cleanup costs. The market potential for remedial techniques based on nanoparticles has been estimated to be US$ 2.4 billion in 2010 (Rickerby 2007: 25). Given the vast scale of contamination, it is thus little wonder that these techniques attract the attention of authorities, practitioners and industries liable for the cost of remediation.

Nano-remediation is no panacea for the problem of contamination, however. Beyond the technical and engineering glitches that still needs to be worked out, more fundamental questions relate to the behavior and fate of nanoscale particles once they have been released to the environment. One concern is for example that unreacted iron particles can migrate from treatment zones and cause harm to the surrounding environment. Other concerns arise over the unknown effects of nanoparticles on plants, animals or ecosystem processes; to what extent they are toxic and what organisms are affected; how they behave and move over time in the air, water or soil; whether they persist and accumulate in the environment and so on. Until more is known about their possible impacts on human health and the environment, caution is in short merited before nanoscale materials are realized on a broad commercial scale (RS and RAEng 2004: 45f.).

Reactions from governments in America and Europe to the promises and uncertainties of nano-remedial techniques can best be characterized as cautiously optimistic. In 2004, the British government for example requested that industry avoid the deliberate release of nanoparticles into the environment – including for remedial purposes – until their effects and possible risks have been assessed. Similar calls for further risk research have been voiced by other governments. While political reactions thus are largely comparable, the responses of practitioners and businesses differ internationally. In the United States, nano-remediation is rapidly emerging as a lucrative new market for commercial operators. In Britain, by contrast, industry has in effect observed a voluntary moratorium on nano-remediation since 2004. A recent survey among UK practitioners found little evidence to suggest that this situation is about to change: responses from a mix of UK-based and international operators revealed no imminent plans for the use of nano-remedial tools; nor did respondents anticipate that such techniques would be used in Britain in the foreseeable future (Bardos *et al.* 2011). Respondents however also reported that their company had undertaken remedial projects using nanoscale iron particles in other countries or that such projects were in progress. And that research to develop and assess the technique, including field trials, were under way in the United States, Australia and various European countries – but not in the United Kingdom. How might we account for these responses? Why do companies observe a voluntary moratorium on nano-remediation in Britain, but not in other countries?

A number of factors might reasonably explain the discrepancies between the UK plans of practitioners and their international business strategies. The scale and nature of environmental contamination in Britain might for example render nano-remedial tools inappropriate for practical applications or irrelevant from a commercial perspective. Or perhaps HM Government has neglected to provide the financial incentives and funding opportunities that could make nano-remedial research and development appear attractive to operators. Or perhaps administrative barriers in Britain inhibit the use of novel techniques for environmental remediation. Upon closer inspection, however, none of these factors seems to account for why companies abide by a voluntary moratorium. Once known as the 'Dirty Man of Europe', Britain has more than its fair share of toxic wastes and contaminated sites just waiting for cleanup to commence. For the entrepreneurial company, the business opportunities for nano-remedial tools in short abound. Funding for nanoscience – including research into environmental applications – is similarly no less generous in UK than in other countries (Palmberg, Dernis and Miguet 2009). While the use of new substances for environmental remediation finally requires administrative approval, the licensing procedure is not excruciatingly bureaucratic or burdensome by international standards. Nor has HM Government established new administrative measures that might deter commercial applications or otherwise dissuade companies from using nano-remedial tools in Britain – at least none that sets the UK apart internationally. Official policy in fact consists merely of a request that industry refrain from the deliberate release of nanoparticles into the environment. Nonetheless, no project applications have been received to date. If not motivated by technical, financial or administrative obstacles, how can we account for the voluntary moratorium observed by industry in Britain? Caution on part of governments we might expect. But businesses exist to generate value for their shareholders. Given the market potential of nano-remediation, why do UK and international companies avoid these tools in Britain? Why do these same companies not observe a moratorium in other countries? What role did the official recommendation play in convincing companies to refrain from the deliberate release of nanoparticles into the environment – and why?

Let me hasten to assure the reader that this thesis is not an account of the techniques of environmental remediation or the science behind the manufacture of nanoscale iron particles. Nano-remediation instead serves as a readily accessible illustration of the uncertain promise and unknown risks of nanomaterials – and the intricate dilemmas confronting policy-makers and governmental risk managers. At the same time, the example also highlights the engine that drives my inquiry: *i.e.* the observation that comparable state policies have met with widely varied business responses. In this thesis, I ask how governments have sought to regulate the possible

human health and environmental risks of nanoscale materials and I examine the policies they develop to assess and control chemical hazards. But above all, this is a study of the role of business in regulatory politics. I ask what businesses want from the regulatory process and investigate the strategies and tactics they adopt to advance their interests. I further ask why industries in some countries embrace self-governing responsibilities, while others do not. This thesis thus constitutes an inquiry into the drivers of business behavior in regulatory politics. To answer these questions, I look to the institutions that underpin relations among state bureaucrats and national industries. I argue that the capacity of state bureaucrats to credibly commit to regulatory outcomes shapes the political behavior and strategies of business.

In a wider theoretical perspective, I make two claims with respect to the regulatory behavior and interests of business. First, fear of state intervention need not be the dominant concern or driver of business behavior. State regulations can of course increase business costs and punish wrongdoing – but they also serve as guidance to expected behavior. In areas of high scientific, technical and legal uncertainty, industries therefore usually have reasons to welcome regulatory decisions and outcomes that can help them navigate an uncertain business environment. Second, and for this reason, industries are willing to share information about their operations – even in the absence of structural constraints on state capacities to intervene – if disclosing such information succeeds in convincing state bureaucrats to make decisions that either reduce anticipated costs or increase private benefits. Companies will however only volunteer information to state bureaucrats if they are confident that the information will not be used to the detriment of their interests. Whether companies will decide to disclose, bias or conceal information depends in short on the expected behavior of their regulatory adversaries. The nature of bureaucratic commitments will thus figure prominently in corporate risk-benefit calculations.

The empirical backdrop against which I pursue these claims is the regulation of nanotechnologies. Nanotechnology refers to particles and products at the nanoscale[2] as well as the techniques used to manipulate, visualize, and characterize materials at this scale. Nanotechnology – or nanotechnologies – is thus not a single technology, but consist instead of a heterogeneous group of engineered particles that have little more in common than their tiny size. Compared to materials in their bulk form (macro and micro), the same materials at the nanoscale can exhibit completely different chemical reactivity, electrical conductivity, strength, mobility, solubility, magnetic and optical properties. Depending on their size, gold particles can for

[2] To illustrate the dimensions involved, a single human hair is about 80,000 nanometers wide, a red blood cell is approximately 7,000 nanometers wide and a water molecule is almost 0.3 nanometeres across.

example appear red, blue or gold in color. The purposeful and precise manipulation of atoms and molecules promises numerous applications that can provide superior price-performance ratios, manufacturing cost advantages, product differentiation – or enable altogether new products and processes (NSTC 2000; Bowman and Hodge 2007).

A first generation of nanomaterials and products began to enter commerce around the millennium and the global market for nanotechnologies has since grown at staggering 20 percent per year.[3] Despite insistent buzz of a trillion dollar nanotech market by 2015 (NSF 2001; Lux Research 2004; Cientifica 2008), the current market value, while unknown, nonetheless falls far below this optimistic mark. Recent market research thus pegs 2010 global sales of nanomaterials at roughly US$ 25 billion (European Commission 2012: 10). The surge of new startups and the diversification of established businesses into nanotech applications are meanwhile expected to create an estimated 2 to 10 million new manufacturing jobs. Little wonder then that nanotechnologies attract large and rapidly increasing public and corporate investments,[4] with global R&D funding reaching 11.8 billion dollars in 2006 (Palmberg, Dernis and Miguet 2009). These are big figures indeed for such small particles.

Many of the same traits responsible for the political and commercial appeal of nanomaterials however – their small size and dynamic properties – also raise unfortunate and uncomfortable questions about their human and environmental effects given their capacity to penetrate and react with biological systems. A number of studies have for example noted similarities in the size and shape of carbon nanotubes (CNT) – one of the most commercially promising and widely researched nanomaterials – and asbestos fibers, an infamous carcinogen. Despite a decade of safety research, answers to important questions remain elusive. Little is in fact known about the toxicological and epidemiological effects of nanomaterials, their fate and transport in the environment, their exposure pathways, whether they persist and accumulate in food chains or how they might interact with other chemicals. The promise of the technology itself – that materials at the nanoscale can exhibit novel and unpredictable properties – thus raises serious concerns over the capacity of existing risk management systems to guarantee human health and environmental integrity.

[3] As an illustration of the rapid rate at which nanotech is being brought to market, by March 2011 the Consumer Product Inventory, which tracks nanotechnology-based consumer products, had grown by nearly 521 percent (from 212 to 1317 products) since it was first released in March 2006. Source: www.nanotechproject.org/inventories/consumer/analysis_draft/ [Accessed August 31, 2013]

[4] In the United States, for example, the accumulated investment under the Federal National Nanotechnology Initiative represents the biggest single investment in science and technology since the Space program.

Nanomaterials are not of course in any sense unregulated. States intervene heavily to control chemical hazards. State control regimes were however enacted long before the prospect of nanotechnologies was yet on the horizon. Given the state of knowledge at the time, statutory controls were designed to assess the toxicity of bulk not nanoscale materials: the risk assessment criteria, regulatory oversight triggers, toxicity parameters, and threshold minimums outlined in extant regulations may therefore well be unsuited or inadequate to assess and control the risks of nanomaterials (Maynard 2006; Pelley and Saner 2009). Current standards for example have as an unstated premise that the larger the dose, the greater the risk. But quite the opposite could in fact be true for nanomaterials: under certain conditions, nanoparticles cluster to form larger particles. The more they cluster, the lower their potential to penetrate skin or cause other kinds of exposure. In contrast to the premise of current standards then smaller doses might imply greater risks (Davies 2007: 14).

The pervasive uncertainties about risks, benefits, properties and future directions of nanotechnologies are widely recognized as demanding a regulatory response to ensure that any potential hazards are effectively controlled. With the advent of nanotechnologies on the regulatory agenda, the question facing regulators, industries and other stakeholders was in other words not *whether* the state should intervene to guarantee public health and safety, but *how*. Although quick to embrace the economic potential of nanotechnologies, governmental control strategies have from the onset been frustrated by information deficiencies in at least three key areas: the paucity of scientific data on the properties of nanomaterials, the speed of development within the field and its heterogeneous nature (Davies 2006; Bowman and Hodge 2008). Most of the information required for a comprehensive risk analysis of nanotechnologies is inaccessible to governments, either because the requisite technical and scientific knowledge simply does not exist or because relevant product and process details are widely dispersed among nanomaterial producers and users. In fact, most

> "regulatory hurdles are currently insurmountable because we still do not know exactly what 'nanotechnology' means or encompasses, much less what concrete risks it may pose. 'Nanotechnology' is a poorly defined, insufficiently understood set of diverse products, processes, and technologies that is not easily captured by any existing regulatory definition, model or system." (Marchant, Sylvester and Abbott 2010: 124f.)

Governments across the world have consequently devoted substantial resources to shore up the knowledge base. Beyond considerable increases in public funding and support for safety research, a core element of American and European nanotech policies has consisted of encouraging dialogues, cooperation and knowledge exchange among government, industry and other stakeholder groups to inform the development of policies and regulatory controls. The

policy process has in other words created ample opportunities for private interests to mobilize and influence regulatory decisions and outcomes.

Conventional wisdom would lead us to expect that industries in liberal market economies should react alike to similar state policies; and that this response in turn should differ from the strategies adopted by their competitors in coordinated market economies (Hall and Soskice 2001). We might in other words expect American companies to react like their UK competitors; and that German and Danish companies adopt similar strategies to influence the direction of national nanotech policies. Confronted with comparable governmental preferences and strategies, industries in these four countries have nonetheless responded remarkably different: dissociation from regulators in the United States, acquiescence and adaptation in Denmark, and close, informal cooperation with government officials – combined with the launch of codes of responsible conduct – in Britain and Germany. The varied business responses to similar state policies are in short puzzling and invite a closer inspection of the institutional drivers of corporate strategies to influence regulatory decisions and policies. Why did the responses of American and British companies differ? Why did German and Danish companies not react alike? Students of comparable politics usually portray Britain and Germany as contrasting cases; so how can we explain the coincidence of business responses observed in these two countries? How can we account for the codes of responsible conduct launched by the British and German industries? Why were no similar initiatives undertaken in the United States and Denmark?

These questions are the concern of this chapter and its six companions. Combined they provide an account of the role of industry in the regulation of nanotech, the determinants of business strategies in regulatory politics and the ability of governments to assess and control chemical hazards. This chapter proceeds to introduce the economic stakes of chemical companies in nanotechnologies. Section two considers the role of information and business interests in regulatory politics. Sections three and four briefly sketch my theoretical arguments, followed by section five which explains the empirical strategy. Section six presents an overview of the findings, while section seven outlines the road ahead.

NANOTECHNOLOGIES AND THE CHEMICAL INDUSTRY

Hailed as the basis for the next industrial revolution, nanotechnologies already find applications in almost every economic sector from energy, electronics and semiconductors over cosmetics, pharmaceuticals and health care to textiles, automotive, construction, food and agriculture. Looking across industries and market segments, however, it is striking how R&D spending in

particular targets application areas within the chemicals and allied industries. This is to be expected: in business terms, nanomaterials, from nanoparticles to nanotubes, are no different from other types of specialty chemicals. Chemical companies are the major manufacturers – and users – of nanomaterials, currently in the form of bulk nanoparticles, such as titanium dioxide, iron or silver, but eventually, as the technology matures, also more advanced functional materials (National Research Council 2006; Renn and Roco 2006). Applications of nanotechnologies in downstream industries meanwhile depend on the raw materials and intermediate products supplied by the chemical industry. Although nanomaterials account for only a tiny fraction of the total volume of chemicals manufactured, production is expected to increase significantly over coming years (RS and RAEng 2004: 71). Chemical companies are now heralding nanotech as the industry's potential savior (Lux Research 2004: 191). With both direct and indirect links to almost all industrial sectors, the industrial chemicals sector is one of the most central and diversified industries of the modern economy. So why are nanomaterials so important to chemical companies?

Industrial chemicals have long ceased to be a growth business. For the past two decades, share prices of major U.S. chemical corporations have underperformed the S&P 500 average (Lux Research 2004: 191). In the 1960s and 1970s, new synthetic materials, such as nylon and polyester, helped fuel the growth of chemical companies, making them Wall Street darlings. But the industry has since stalled. By 1980, chemistry science was no longer producing the breakthroughs, which had marked chemicals as a growth industry, since its origin in the late 1800s (Chandler 2005). While R&D intensity in the chemical industry remains well above the industrial average, technological maturity translated into fewer innovations and diminishing returns to research and development. It is estimated that there has been a 90 percent decline in product innovations for bulk or commodity chemicals since 1965, with focus instead turning to cost control through process innovation (Albach *et al.* 1996). Since the 1970s, the cost of introducing new substances has risen sharply, and innovation has progressively become the domain of large companies: in 1983, four companies accounted for over 60 percent of R&D spending for industrial chemicals, with DuPont alone responsible for one fourth (Davies 1983). While these general trends disguise significant variations across subsectors, growth at disproportionately high rates, rapid innovation and technological change – characteristics of the postwar period – has undeniable come to an end. Nanotech and the development of new materials now for the first time in decades promise new product lines and business opportunities.

Nanotechnologies are expected to usher in a profound 'paradigm shift' in the chemical industry. Success in the chemical industry used to be limited by size and scale of operations. High

barriers of entry meant that small companies rarely had a chance of competing, rendering the industry traditionally one of the most inhospitable environments for small startups. Akin to the invention of recombinant DNA, which created the modern biotech industry and profoundly altered the business model of the pharmaceutical industry, nanotechnologies are set to change this by transferring the success function from 'scale of operations' to the 'creativity of the scientist' (Lux Research 2004). Making nanomaterials is in fact not altogether that difficult: 50 dollars worth of raw materials and equipment will suffice to produce a few thousandths of a gram of nanoparticles. In principle, a few people working out of a garage or a professor and some grad students is all that is require to establish a highly innovative startup (Cientifica 2008); and indeed startups and university spin-outs experimenting with various applications of nanomaterials abound.

While startups now serve as important catalysts of innovation, large chemical manufacturers are meanwhile well-positioned to reap the benefits of nanotechnologies. Many nanomaterials and applications have been developed by specialist companies that have only the ability to produce small quantities required for research. No sane company however would base a major product on a nanomaterial made by a financially precarious startup. Scaling up production without scaling up cost is not a trivial exercise, and it is not something that can be achieved with the resources and expertise of a small university spin-off. As Big Pharma before them, large chemical corporations are therefore expected to drive demands for in-licensing of novel, innovative products and development-stage acquisitions (Lux Research 2004: 194). Following relative industrial decline and technological maturity, it is thus no surprise that chemical manufacturers have much riding on the success of nanotechnologies. As the to date most radical illustration of the industry's commitment to nanotechnologies, DuPont – the pioneering company of the revolution in synthetic fibers – announced the sale of its nylon, polyester and lycra businesses to Koch Industries in November 2003. As other chemical leaders, DuPont instead wagers hopes for future innovations and higher profits on the ability of nanotech breakthroughs to rejuvenate the industry (Zhao, Boxman and Chowdhry 2003). Regrettably, for DuPont and its competitors, storm clouds are gathering as increasing consumer skepticism and calls for governmental regulation threatens to bring the nanotech innovation boost to an abrupt end.

REGULATORY POLITICS AND BUSINESS INTERESTS

For all their novel properties, nanomaterials are from a regulatory perspective familiar in at least one respect: the paucity of reliable information on which to base protective standards. To assess

and control the uncertain risks of nanotechnologies, state authorities require vast amounts of scientific, technical and economic information. Information which regulators do not have – and which can only be acquired with difficulty, if at all. But this is not a predicament unique to nanomaterials. From environmental policy over worker protection to the regulation of competition, state authorities in almost all contexts need more information than they have – and much of the needed information is held only by the very businesses they seek to control.

Government regulation of economic behavior usually finds its justification in three main types of market failures: a lack of competition, externalities, or a lack of full information about products and services (Coglianese 2007).[5] When markets fail, state authorities must collect and process information about the activities of individuals, organizations and industries: to identify whether businesses are acting as monopolists, regulators need information about their marginal costs of production. For regulation that addresses externalities or seeks to ensure adequate product disclosure or safety, regulators need information about the risks created by products and production processes. Information is as Cary Coglianese and colleagues observe (2004: 277) thus the lifeblood of regulatory politics: "The effective use of governmental power depends on information about conditions in the world, strategies for improving those conditions, and the consequences associated with deploying different strategies." State authorities must in short gather, develop and analyze relevant information about the activities they wish to regulate as well as about available control techniques.

More often than not however the information state authorities require to make regulatory decisions can be supplied only by the very companies and industries they regulate. Companies almost always know much more than governments about the risks associated with their products, technologies and processes (Grant, Paterson and Whitston 1988: 60f.; Wagner 2004: 1642). For many issues and problems, governments can of course learn as much as, if not more than, industry. When state intervention is needed to protect the public from harms arising largely independent of economic activity – such as infectious diseases or natural disasters – the relevant information can be acquired by governments or independent researchers as easily as by industry (Coglianese 2007: 187). General scientific expertise is however rarely sufficient when state agencies look to control particular industry practices or harmful products. And it is often impossible for governments to conduct independent research to replicate the information held by private actors. Companies learn through their own testing and analysis, from reports of

[5] Although nanotechnologies might conceivably implicate any and all of these market failures, the most salient concerns arise over externalities and information asymmetries (Coglianese 2010).

complaints by customers or workers, or simply based on their superior understanding of the properties of their products and the occasions for exposure to them (Coglianese, Zeckhauser and Parson 2004: 286; Applegate 1991). The best source of information about the risks of particular products and processes, the activities of companies, the costs of remediation or mitigation, or the feasibility of different control technologies is in other words the regulated industry.

State authorities cannot count on self-interested holders of information to reveal it fully and without bias. Neither can governments always count on their powers to compel disclosure of information. But while manufacturers may have an interest in sharing favorable, self-serving information,[6] they have little incentive to produce, disclose or otherwise assist in the acquisition of data that would help governments regulate (Lyndon 1989). When information is sorely incomplete, controverted, or effectively unobtainable, states face intractable difficulties in deciding how to intervene against suspect products and activities. Industries bend on reducing state interference are therefore best advised to minimize available information about their operations. That industries have reasons to resist cumbersome regulations hardly needs elaboration. Although their rationales may differ, companies of all sizes and colors share undeniable interests in rejecting statutory obligations that could result in increased operating cost, delays on market entry and so on. Fear of state intervention in other words cautions against supplying truthful information that would make it easier for state authorities to impose costly new regulations.

But business also has preferences for and stakes in the outcomes of regulatory politics that extends beyond a mere desire to minimize state intervention. A classic tenet of the Economic Theory of Regulation is thus that an industry might actively seek regulation – just as it may be thrust upon it. In this view, the state is both a potential threat *and* resource to industry. As succinctly expressed by George Stigler (1971: 3): "as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit." We need not subscribe to this view however to appreciate that businesses can value certain regulatory outcomes. More recently, the varieties of capitalism literature has for example emphasized how national industries look to state policies to maintain, enable and reinforce the institutional competitive advantage upon which they rely. Since many of the institutions that allow companies to coordinate their behavior depend on the regulations governments promulgate, businesses in liberal and coordinated market economies alike have fundamental stakes in securing state policies that are incentive compatible

[6] Such as information showing that the likely costs of a new regulation would be higher than government anticipates or that the likely benefits would be lower (Coglianese 2007: 187).

with – that is, complementary to the existing modes of coordination (Hall and Soskice 2001; Hall and Thelen 2009: 16f.). A similar conclusion applies with respect to risk regulation: industries clearly have reasons to resist draconian environmental, health and safety regulations; but important benefits can also accrue from state intervention.

When there is a clear legal framework associated with a given range of economic activities, businesses are better able to identify and quantify commercial risks. A predictable regulatory environment can for example help companies avoid undertaking expensive and long-term R&D for applications, which may later be banned. In a stable business environment, investors and lenders are more forthcoming in offering financial support and insurers are more willing to offer coverage for potential liabilities. A mix of scientific and regulatory uncertainty can in contrast combine to significantly impair the economic prospects of an industry. Absent official guidance, companies are uncertainty about their obligations, leaving them potentially liable should manufacturing processes or products later be discovered to cause harm to humans or the environment. Consumers and business partners similarly prefer to buy tested and safe product; but will tend to shy away from products with unknown effects or uncertain risks. Without statutory guidelines, however, companies cannot effectively demonstrate the safety of their production processes and products. To survive and prosper, industries in short require a stable and predictable environment in which to orient their operations; and they therefore have reasons to welcome regulatory outcomes that can help them navigate an uncertain environment. The inconclusive status of nanomaterials under existing statutes and regulations in other words presents opportunities and predicaments beyond a mere desire to reduce state interference.

BUREAUCRATIC COMMITMENTS AND BUSINESS BEHAVIOR

In this thesis, I argue that the varied responses of industries in America and Europe result not from variations in governmental control strategies for nanotechnologies or from different stakeholder perceptions of nanotech, but from differences in the capacity of state bureaucrats to credibly commit to cooperation with industry. In areas of high scientific and technical uncertainty, such as nanotechnologies, new information can exercise significant influence on agency agendas, priorities and policies. This can work in industry's favor, if disclosing information succeeds in convincing state bureaucrats to make decisions that benefits industry. With the promise of influence, companies may therefore readily volunteer information, share their expertise and actively assist regulators in the acquisition of new knowledge. Cooperation can in other words serve industry's interests as well as regulators' needs.

But cooperation is also a dangerous course for industry: while regulators certainly appreciate information volunteered by industry, they may value the information differently than originally anticipated. Regulatory problems often have several plausible causes, and they almost always have several potential solutions. Companies with a hazy picture of the regulator's overall puzzle may fail to accurately assess the value and impact of any particular piece of information. Seemingly unimportant data could in fact be just the information regulators were searching for to justify stringent restrictions of industry practices, processes or products (Coglianese, Zeckhauser and Parson 2004: 303). Unless industry can trust regulators with information, disclosure is a risky gambit. When deciding among a course of disclosure or nondisclosure, companies must in other words attempt first to anticipate how regulators evaluate the available body of knowledge; second how they can be expected to act on that knowledge; and finally what impact new information will have on agency decision-making. Companies will only volunteer information to state bureaucrats if they are confident that the information will not be used to the detriment of their interests; and cooperation therefore hinges on the capacity of state bureaucrats to credibly commit to respect corporate interests. Whether companies will decide to disclose, bias or conceal information depends in short on the expected behavior of their regulatory adversaries and the nature of their commitments.

The framework I elaborate to dissect the determinants of business strategies draws in important ways on the varieties of capitalism literature. The varieties literature is premised on the existence of distinctive institutions that permit business – and governmental – actors in different types of political economies to make credible commitments to one another (Hall and Soskice 2001; Wood 2001). I begin from a similar premise to explore the institutional arrangements that allow bureaucratic actors to convince companies that they can be trusted with sensitive information. While formal procedures exist to routinize the handling of trade secrets, by and large, the means of protecting confidential information depend on the relationships between regulators and the regulated (Brickman, Jasanoff and Ilgen 1985: 224). Different industry strategies will in other words reflect variations in the institutions, which underpin relationships among industry and state bureaucrats. Countries differ in their regulatory institutions and processes. And they therefore transmit different kinds and amounts of information about the probable future behavior of state bureaucrats to industry. Two features in particular of national regulatory regimes, I argue, are responsible for the capacity of state authorities to commit to cooperation with industry: the regulatory powers of state bureaucrats and their reliance on deliberative institutions in the formulation and implementation of chemical safety policy.

First, political systems differ in how they concentrate or diffuse regulatory powers, and they therefore structure the opportunities to influence regulatory outcomes differently. Concentration of regulatory authority in the hands of administrative agencies dictates a strategic orientation towards the state bureaucrats with the power to decide regulatory outcomes. Independent and insulated state authorities are not easily swayed by changing political and economic conditions, but focus instead on achieving their statutory obligations and objectives. Limits on political interference or judicial scrutiny may thus on the one hand convince manufacturers that a commitment to pursue a set of stable and predictable policies is credible. Absent recourse to the courts or parliaments, representatives of organized interests can on the other hand tread few alternatives paths to influence the direction of regulatory policy. Companies consequently have to win what they can during administrative deliberations. Since information and expertise is the most relevant currency in convincing state bureaucrats (Culpepper 2011), concentration of regulatory powers can create potent incentives for companies to divulge information, if this can be exchanged for influence on administrative decisions and policies.

Second, advisory bodies, which put industrial expertise in permanent and close contact with their academic and governmental peers, create opportunities for participants to improve confidence in the strategies of each other. Policy discussions funneled through such deliberative institutions afford industry representatives opportunities to learn how officials understand scientific evidence and evaluate the need for new controls. Because they increase the amount of information obtained and disseminated among participants, advisory bodies improve the ability of companies to gauge the intentions of state bureaucrats and predict their probable reactions to new information. Confidence in the designs of state bureaucrats can in turn persuade companies to volunteer sensitive information and hence shape regulators' diagnosis of regulatory problems and their possible solutions.

Where companies have reasons to doubt the credibility of bureaucratic commitments, they must in contrast remain vigilant to possible concealed agendas or the prospect of political or judicial interference in regulatory proceedings. Nondisclosure is in short a rational business response, when state bureaucrats cannot credibly commit to respect the interests of industry. In chapters three through six, I demonstrate how businesses in all four countries responded to the incentives and opportunities embedded in their respective regulatory systems; and how industry self-regulation in Germany and Britain is a response to the policy process that grows organically from a strategy of cooperation with state authorities. To appreciate the motivations for companies to embrace self-governing responsibilities, it is however necessary to briefly consider the reactions to and fate of the technology – biotech – which preceded nanotechnologies.

TECHNOLOGY LOST AND THE SELF-GOVERNANCE OF NANOTECH

In 2003, the European Union adopted a new set of regulations governing the approval and sale of genetically modified organisms. Preceding the enactment of Council Regulation 1829/2003 was a decade fraught with intense policy disputes, unilateral restrictions or bans by individual Member States on GM products that had been approved by the EU, vocal opposition from the NGO community, consumer boycotts, and highly negative media coverage, resulting in deteriorating public acceptance of GMOs in food, suspicion of industry and declining trust in the regulatory authorities charged with overseeing food safety. Since 2003, the EU's stringent labeling requirements, combined with widespread consumer rejection, have prompted virtually all food producers and retailers to refrain from using or selling GM foods that would be required to be labeled as such. Few GM foods have been approved for commercialization, the number of field trials has remained low and practically no GM crops are commercially grown in the EU (Bernauer and Meins 2003: 652f.; Vogel 2012: 81). Prior to the GM Controversy, policy-makers, scientists and biotech firms saw in the technology the basis for a second Green Revolution. Dashed by a perfect storm of anti-GM sentiments, abandonment by business partners, and onerous regulations, culminating in public backlash and technology stigma, these hopes never came to fruition. The scene and timing for nanotechnology's arrival on the regulatory agenda in 2003 could thus hardly have been more inauspicious.

Nano is not GM. But as another technology with revolutionary promise – ultimate human control of the very forces of nature – nanotech entails all the ingredients for visceral public reactions and market rejection. Much writing on nanotech governance thus emphasizes the need to heed the lessons of GM. Foremost among these is the need to ensure public acceptance of nanotechnologies and market confidence in industry. If nanotech is to avoid the fate of GMOs, stakeholders – business partners, investors, insurers, employees, the media, and especially customers and the public – need to be reassured that companies commercializing nanotechnologies are proactively and effectively mitigating any risks related to them. I suggest that self-regulation in this contexts should be understood as business strategy intended to garner stakeholder confidence and acceptance of nanotechnologies.

Recognition of the signs of deteriorating acceptance of GMOs in food and growing suspicion of industry came late for the biotech industry; and industry leaders never embraced self-governing responsibilities as a response to mounting public skepticism. Proponents instead – mistakenly – assumed that rational arguments could influence the response to the technology. While markets and consumers certainly did come to appreciate the revolutionary new drugs associated with advances in genetic engineering, those very same scientific principles applied to

crops and food unleashed a barrage of anti-GM sentiments. Public hostility, backlash and technology stigma in turn compelled politicians to entrench these sentiments in official policy (Sylvester, Abbott and Marchant 2009). The misfortunes of the European agri-biotech industry thus constitute a cautionary tale for the nanobusiness community – a looming fate that industry leaders on neither side of the Atlantic have a desire to share.

Confronted with ostensibly similar challenges, industries in America and Europe have nonetheless drawn different conclusions from the GM Controversy: whereas the British and German industries have responded to the dangers of 'nanophobia' by endorsing codes of responsible conduct, comparable initiatives are conspicuously absent in Denmark and the United States. I argue that the roots of these diverging self-governing strategies lie with the different roles companies have assumed in the regulation of nanotech. Regulatory policies decided through mutual agreement and joint collaborations imply that state bureaucrats and companies both have a stake in the final outcome; and inevitably that they must share the political risks of such decisions. This is however treacherous terrain for industry: because consumers and other stakeholders do not or cannot distinguish among members of the 'nano' industry, companies will tend to assume a collective identity in the public's eye. Adverse information about the products or activities of one company will consequently color perceptions about the entire industry and the technology as a whole. If left undisputed however regulatory and scientific developments could trigger visceral market reactions as happened for the agri-biotech industry. The predicament facing industry is therefore one of managing stakeholder perceptions of nanotechnology risks and benefits; and codes of responsible conduct can be understood as instruments to reassure stakeholders that regulatory decisions do not reflect the inherent harmful properties of nanotechnologies. Industry self-regulation in Britain and Germany thus does not intend to *preempt*, but *complement* state intervention.

THE EMPIRICAL STRATEGY

This thesis recounts the roots of the varied responses of industries in Britain, Denmark, Germany and the United States to the regulation of nanotechnologies; and its research strategy thus grows from the broad question: what determines business behavior in regulatory politics? Business behavior and strategy result from multiple, often interwoven conditions and circumstances, the most obvious of which are to be found within the corporation itself (Getz 1997; Coen, Grant and Wilson 2010). To account for the diverging responses of companies in America and Europe, I however look to the institutions that underpin relations among state

bureaucrats and industry. Accordingly, I investigate how governments in the advanced industrial economies have sought to regulate nanoscale materials and their possible risks to consumers, workers and the environment; and review how industries in different regulatory contexts have responded to the policy process. To understand the impact of regulatory institutions on business behavior, we need to examine their links to the strategic risk-benefit calculations of companies. In consequence, I undertake a controlled comparison of the institutional drivers of business responses through two case studies contained in chapters four and five: chapter four contrasts the dynamics of regulatory policy-making in Britain with the United States, while chapter five compares the nature of regulatory politics in Germany to Denmark. And, the question I ask of each case is thus: how have the institutions of national regulatory systems shaped the response of industry to the policy process?

The arguments I elaborate and test in the empirical chapters draw on extant theories of business behavior in regulatory politics. As I observed above, the varied industry responses to comparable state policies nonetheless elude predictions based on conventional political science wisdom. And the case studies therefore at the same time serve a heuristic purpose: hence, while the four cases primarily serve as vehicles to assess my theoretical arguments, the empirical analyses also raise new questions about the drivers of business behavior in these four countries. I take these questions as opportunities to further probe the roots of the diverging industry responses; and the cases studies as a result also serve to clarify and refine my initial arguments. The methodological approach I use is thus one of theory-driven, inductive inquiry (George and Bennett 2005: 20ff.).

The manufacture and use of nanomaterials are potentially subject to multifaceted programs of intervention under both general pollution control laws and legislation directed at specific product categories. While efforts are gradually under way to control specific applications of nanomaterials in legislation governing food safety, cosmetics, pharmaceuticals and pesticides, I focus on chemical management frameworks; that is, the policies regulating industrial chemicals and their risks in the workplace and the environment. The main source of exposure to manufactured nanomaterials is in laboratories and other workplace settings. Governments, businesses and other stakeholders have therefore on the one hand displayed particular interest in controlling sources of occupational exposure. Notification and premarket testing requirements will on the other hand dictate how nanomaterials are regulated further downstream. Whereas nanomaterials in their role as food additives or drug delivery systems are subject to frameworks controlling end products, chemical safety laws are largely 'front-loaded' statutes that provide state agencies with the authority to review chemicals before and during their use. Chemical management frameworks

form the initial basis for obtaining the safety-related information that is passed along the supply chain. Absent such information, employers and downstream users cannot undertake proper hazard assessments in accordance with health and safety legislation. The extent and nature of regulatory controls upon the introduction of nanomaterials will consequently prove influential in determining whether and how they will fall under the scope of other consumer and environmental protection statutes (Frater *et al.* 2006).

In order to control for sector, market and industry specific characteristics, I devote particular theoretical and empirical attention to the chemical industry. Other industries that use nanomaterials are to some extent subject to national chemical management frameworks. Any developments relating to the control of nanomaterials will however primarily impact on chemical companies. Given the level of R&D intensity, any occupational safety measures will weigh prominently on chemical manufacturers. Similarly, new testing or notification provisions will disproportionately affect the interests of chemical companies. As the primary targets of regulation, it therefore no surprise that representatives from the chemical industry have dominated efforts by business groups to influence the direction of the evolving regulatory framework for nanotechnologies. Yet, despite this common, overarching goal, industry leaders and corporate representatives have nonetheless set about achieving it through remarkably different strategies. Internationally, business responses thus range from close cooperation with state authorities over dissociation from regulatory officials to acquiescence and adaptation to state policies.

To understand the unlike responses of industries in America and Europe, the thesis relies on a comparative research design. Chapter three tracks the evolution of state control policies in Britain, Denmark, Germany and the United States over the decade from 2003 to 2013 and compares the role of industry in the policy process. The four cases were selected in order to ensure a rigorous assessment of my arguments across similar and different cases. The four countries have, firstly, emerged as prominent voices in the international nanotech debate; and as such their nanotech policies encompass the broad catalogue of strategic initiatives, research investments and risk management instruments OECD countries have fielded to assess and control the risks of nanomaterials (OECD 2006; 2008; 2012; 2013). The four countries thus on one hand provide a representative sample of how governments in the advanced industrial economies have responded to the uncertain promise of nanotechnologies (Seawright and Gerring 2008: 299f.). As their control strategies moreover are largely comparable, we are on the other hand also afforded a measure of control for the effect of state policies on corporate risk-benefit calculations.

Equally important, the cases secondly capture a wide and varied spectrum of business behaviors, tactics and strategies. Efforts to design appropriate control policies are beset with uncertainties, and the high stakes riding on such decisions easily engender political controversy. While the regulatory process in most countries admits the views of nongovernmental participants, the opportunities and incentives to share information with regulators differ. Active cooperation with state authorities may allow companies to mold regulatory policies to their strategic advantage. But companies must also be cautious of sharing information that risks the impositions of adverse regulations. Differences in the extent, format and timing of participation in the policy process thus hints at variations in the strategic risk-benefit calculations of companies. As I document in chapter three, the four cases offer ample instances of collaboration with or dissociation from governmental officials, disclosure as well as nondisclosure, business self-governance and its absence; and the cases studies allow us to explore the various paths through which these outcomes came about (Mahoney and Goertz 2004).

The logic of my argument should finally lead us to find an empirical relationship between the institutions of domestic regulatory systems and the strategies of national industries. The four countries were therefore sampled to assess how different institutions impact on business behavior and at the same time control for alternative explanations of the observed outcomes. The empirical chapters match the four countries in pairs on major political and economic dimensions to control for their possible confounding effects on business behavior (King, Keohane and Verba: 202-206) and consider how variations in the regulatory environment for nanotech have influenced the responses of national industries. Chapter four on Britain and the United States thus varies the regulatory powers of state bureaucrats, while chapter five investigates the effects of deliberative institutions in Germany and Denmark. Given their distinct approaches to chemical control policy, the country pairs allow us to explore the links between different institutions and their effects on corporate decisions to disclose, distort or withhold information from state bureaucrats.

Interactions among regulatory authorities and companies of course do not occur in a vacuum: the political strategies of business grow from deeply rooted traditions of state-society relations and the distinct organizing logic of political economies. We therefore need to untangle the impact of general business-government relations from the specific effects of regulatory institutions. To make inferences about the institutions and processes of chemical control, we must in short be confident that they exercise an effect on the behavior of companies, independent of distinct state-society traditions or the particular history, organization, and economic strength of national industries. Beyond variations in their institutions and processes of chemical control policy, the

country studies juxtapose broadly similar cases. And the case studies thus approach the question of control for confounding variables according to the logic of *most similar systems* (Lijphart 1971; 1975).

Classifying patterns of interactions among business and government in advanced industrial economies has long been of particular interests to students of comparative political economy. Whatever classification scheme is employed, however, Britain and the United States are invariably placed in the same category. And, while perhaps relatively unfamiliar to the comparativist, Denmark is usually grouped together with Germany. Since the country studies contrast parallel processes of nanotech regulation in the liberal Anglo-Saxon countries and the continental *Rechtsstaats* of Germany and Denmark, we can thus firstly feel confident that variations in industry strategies do not merely represent calculated attempts to counter different bureaucratic or legal traditions. Second, the legacy of 'corporatist-style' negotiations between major interest groups and the state in Germany and Denmark would rule out different modes of interest intermediation as the source of variation; as should the prevalence of pluralist modes of interaction in the United States and (to some extent) Britain.

Neither should, thirdly, variations in the organizing logic of the four countries' political economies present serious problems for drawing valid inferences. Although neither Britain nor Denmark may represent 'pure' types (Howell 2007; Campbell and Pedersen 2007), they do nonetheless fall squarely within the group of liberal and coordinated market economies, respectively (Hall and Soskice 2001; Hall and Gingerich 2009). Variations in regulatory strategies – whether governmental policy proposals are incentive compatible or not – should thus not reflect the gravitation of national industries towards the modes of coordination for which there is institutional support. The case studies would in short appear to provide a good comparative fit (Lijphart 1971): since the organization of their political economies and their traditions of state-society relations are comparable, any difference in industry strategies is likely to reflect differences in the organization of their national chemical control regimes.

The gentle reader might reasonably object that the case studies also contrast countries with very different political systems. Might not the federal American system, for example, create different opportunities for businesses than the unitary British system; opportunities which could have a different bearing on the political strategies of companies in the United States than in Britain? Relationships among regulatory authorities and business actors constitute one dimension, albeit an important one, of a nation's public policy process. The influence of business organizations inside political parties, political and constitutional constraints on the autonomy of national governments or policy-making procedures decentralized enough to allow business

groups many points of access and some veto points all weigh on the strategic risk-benefit calculations of companies. Precautions must in other words be taken to ensure that conclusions drawn from the country studies are indeed valid and not a spurious effect of some omitted feature of these cases (King, Keohane and Verba 1994).

This is an endemic problem in comparative research. My approach to the problem is to explicitly consider the most important alternative explanations that might be relevant to the observed patterns of interactions in the four countries (in particular legislative developments, public opinion, the political and economic strength of national chemical industries, and the impact of EU competences on regulatory decision-making). As Peter Hall (2008: 310) emphasizes: "One secures a more stringent assessment of the validity of a theory by comparing how well it explains the facts one observes with how well another theory explains such facts." To anticipate the results of chapters four, five and six, neither of these rival accounts offers a satisfactory explanation of the varied business responses in Britain, Denmark, Germany and the United States. In each country, industry strategies, including the decision to self-regulate or not, flow from the specific configuration of institutions that underpin relations among state bureaucrats and industry. The possibility of comparisons *across* the case studies and the existence of *within* country variations in industry strategies further bolster our confidence in this interpretation and our ability to draw causal inferences about the determinants of business behavior in regulatory politics (Hall 2003; George and Bennett 2005).

Effective causal inference requires bringing to bear as many kinds of evidence as possible (Collier, Brady and Seawright 2004); and the case studies labor to systematically consider information about actors and their interactions, the unfolding of events leading to the observed outcomes as well as about alternative mechanisms, which might have produced these outcomes. The case studies bring together some 25 expert interviews with official documents and secondary literature. The analyses seek to triangulate these different sources to arrive at more valid and reliable interpretations of each case. The empirical backbone of the analysis is the burgeoning body of written evidence produced as a direct result of the evolving nanotech debate. Scientific reports, technical policy documents and other official publications provide a generous source of information about the design and progress of strategic initiatives, research programs and risk management policies as well as the extent, format and timing of industry participation in the policy process. The case studies further draw on a broad array of internal working documents, meeting minutes, position papers, written comments, testimony and transcripts to recreate policy deliberations, priorities and decisions. Information about national chemical control regimes was gleaned from official documents outlining policy mandates, statutory obligations, regulatory

competencies and processes. Documents were in the main accessed through official websites; and the case studies make extensive use of this 'paper trail' to reconstruct policy rationales as well as to trace interactions among regulators and business representatives.

The case studies are further enriched by information drawn from country surveys and policy reviews, statistical data, press coverage and similar secondary sources. Summary reports and country profiles were likewise consulted to garner information about the history, organization and operations of national chemical industries. Nanotechnology meanwhile attracts considerable scholarly attention; and academic publications proved a valuable source of additional insights about the unfolding of the four countries' regulatory processes. I moreover reviewed a diverse range of extant academic literatures to obtain information on business-government relations in the four countries, the nature of regulatory politics and the role of the chemical industry in their respective political economies.

While voluminous, official documents and secondary sources however provide only a partial picture of the regulatory process and corporate risk-benefit calculations (George and Bennett 2005: 99-105). Additional data was therefore collected through 27 semi-structured interviews with representatives from business groups, regulatory authorities and other stakeholders. Respondents were identified among former participants in the regulatory processes and an attempt was in each country made to interview representatives from industry and government as well as third parties to cover multiple views of the policy process.[7] The interviews were designed to obtain evidence about the stakes and motivations of actors as well as the underlying context of the empirical cases; and the interviews thus supplied invaluable information, when official documentation or secondary literature was patchy. The interviews were however above all intended to help root out inconsistencies and ambiguities in the official sources. Interviews with former participants were in consequence used both to facilitate a better grasp of the empirical cases and to systematically test, elaborate and correct conclusions drawn from the written materials. To counter potential distortions of the empirical record, opinions and interpretations expressed during interviews were sought qualified in subsequent interviews and cross-checked against written evidence, where necessary by gathering additional data or consulting new literature. Assertions made in the case studies based on interview material are thus supported by evidence from two or more sources. In

[7] Interviews were carried out between February 2011 and July 2013. As a condition of participation, all respondents were promised anonymity and in-text quotations from interviews are therefore presented in a non-attributable form. Refer to Appendix A for a list of respondents in each country and their affiliations.

the ambivalent cases, the written record was allowed to prevail, with interview statements instead offered to illustrate the positions of various stakeholder representatives.

Throughout I use the available information to assess the congruence of my explanatory framework as well as rival explanations with the observed patterns of interactions. Evidence from the written sources is thus compared with what is known about the nature of regulatory politics in each country and information gleaned from the interviews. The case studies draw on these diverse sources to piece together an account of the policy process in the four countries, the role of industry in the regulation of nanotechnologies and the institutional roots of the varied business responses.

PREVIEW OF THE FINDINGS

The uncertain promise and unknown risks of nanomaterials have led governments in America and Europe to pursue a range of largely comparable strategic measures and policy initiatives. Guided by what can best be described by an ambition of 'getting it right', authorities in Britain, Denmark, Germany and the United States embarked on a regulatory path focused on closing existing knowledge gaps, combined with active participation in international efforts to enable a targeted response to nanotechnologies. To inform their regulatory policies, decision-makers have moreover prioritized initiatives to canvass the views of stakeholders. From an early stage, collaboration with industry was thus in each country recognized as an important strategic measure to advance the regulatory agenda. At face value, then, governmental decision-makers have arrived at much the same diagnosis of the challenges created by nanotechnologies – and their possible solutions.

British and German companies have not hesitated in their response to the opportunities for influence entailed by the invitation for dialogue and cooperation. Companies and their representatives have taken every opportunity to consult and cooperate with state authorities, pressing on decision-makers their concerns about scientific developments, technical feasibility and economic impacts. Regular contacts and dialogue have in turn created the impetus for a range of government-industry collaborations covering joint safety research, exposure assessment and the development of risk management methodologies. Collaboration has allowed decision-makers to access information crucial to gauge the need for immediate action and the formulation of strategic priorities. Industry representatives for their part have sought to nurture and reinforce cooperative relations with regulators, resulting in extensive policy discussions, accommodation of

corporate interests and broad, if not universal agreement on the direction of national nanotech policy.

Although presented with ostensibly similar prospects of guiding regulatory decisions and policies, American and Danish companies have nonetheless been reluctant to embrace the strategies of their German and British competitors. Relations among state authorities and industry have in both countries remained detached and arms' length. In the United States, companies have displayed manifest discomfort in cooperating with the federal regulators. Skepticism regarding the intentions of federal agencies has strongly spoken against a course of volunteering information to regulators. Federal safety research has remained largely detached from parallel efforts in industry, while risk management initiatives have taken shape through internal agency processes. In Denmark, companies have voiced few demands and offered only minor input to the policy process. With little discernible industry mobilization, the Danish policy process has been dominated by state authorities – and the prevalence of irregular and *ad hoc* engagements among officials and industry representatives. Even as a political agreement was concluded in 2012 to introduce new mandatory obligations on industry, business representatives voiced few loud objections or protests. Acquiescence and acceptance of governmental policies are in short words that best describe the response of Danish companies.

ROADMAP

Chapter two elaborates my framework for dissecting the drivers of business behavior in regulatory politics. I first discuss the dynamics of chemical control policy and consider the interests of businesses in the regulation of nanotech. I next explore the political problem of commitments and how variations in the institutions and processes of national chemical control regimes can explain the varied business responses to nanotechnologies. Chapter three examines state policies to assess and control the risks of nanomaterials and documents how companies in Britain, the United States, Germany and Denmark have responded to the regulatory process. I show how decision-makers in America and Europe have adopted similar policy strategies; and how the responses of companies vary across the four countries. Chapters four and five are tasked with explaining this variation.

Chapter four demonstrates how the autonomy of administrative authorities to determine regulatory outcomes, insulated from pressures originating from other branches of government, explains the different responses of industries in the United States and Britain. Disengagement from regulators in the United States and cooperation in Britain are in turn business responses

that grow from the distinct opportunities for influencing regulatory outcomes on either side of the Atlantic. Chapter five recounts the reasons for the diverging responses of German and Danish companies. I show how the responses of companies in the two countries are rooted in the institutions that structure communications among state actors and industry representatives. I further demonstrate how the strategic environment for chemical control policies in Britain and Germany are comparable; and how the coincidence of business responses in these two countries is explained by the capacity of state bureaucrats to commit to cooperation with industry.

Chapter six asks why companies in Britain and Germany self-regulated, while their U.S. and Danish competitors did not. I show how neither the organization of business interests, market developments nor the prospect of new legislation can account for the cross-national variation in industry self-regulation. The chapter instead demonstrates how UK and German companies embraced self-regulation as an instrument to reassure their stakeholders that regulatory decisions and outcomes do not reflect the inherent harmful properties of nanotechnologies. Chapter seven returns to the UK moratorium on nano-remediation. Drawing on chapters four and five, I argue that a voluntary moratorium on the use of nano-remedial techniques is an industry response that grows from the demands placed on corporate decision-makers by the realities of the British regulatory system. The chapter further revisits my theoretical arguments in light of the empirical cases as well as how they might apply to other countries, industries and technologies. I consider possible implications for our understanding of the regulatory behavior and interests of business, and conclude with some reflections on the ability of governments to assess and control chemical hazards.

CHAPTER TWO

Bureaucratic Commitments and the Control of Chemicals

The uncertain promise of nanotechnologies has shaped regulatory debates for the better part of a decade. The, as of yet, unknown risks of nanomaterials are widely recognized to demand a regulatory response. Given the vast financial and political resources invested in nanosciences and technologies, politicians and regulators share obvious interests in ensuring the safe and responsible development of nanotechnologies. The desire to reap the economic, environmental and societal benefits of nanotechnologies has thus led governments to embrace broadly similar policy strategies. Rather than recount the origins of governmental control strategies, the purpose of this chapter is instead to develop a framework that will allow us to dissect the roots of the varied industry responses to comparable state policies. For this reason, the chapter seeks to elaborate the regulatory interests of 'nanobusinesses' and the drivers of their behavior. To understand why industries in America and Europe reacted differently, we must look to the institutions that underpin relations among regulatory authorities and industry; and how the capacity of state bureaucrats to commit to a set of predictable control policies links to corporate risk-benefit calculations.

I develop this argument in two steps. Sections two through five discuss the dynamics of chemical control policy and consider the interests of businesses in the regulation of nanotech. The control of chemical hazards demands vast amounts of scientific, technological and economic information. Information which regulators do not have – and in many instances can only acquire from industry. Companies for their part will only volunteer information to state bureaucrats if they are confident that it will not be used to the detriment of their interests. Cooperation among regulators and industry is thus a desirable, but not inevitable feature of chemical control policy. In sections five to seven, I explore the political problem of commitments and how variations in the nature of bureaucratic commitments shapes the behavior of business in regulatory politics. I explain how concentration of regulatory powers in state bureaucracies and the reliance on deliberative institutions in the formulation and implementation of chemical safety policy can

convince companies to trust state bureaucrats with sensitive information. First a few words on the problems of regulating nanotechnologies are required, however.

NANOTECHNOLOGIES: THE PROBLEM OF KNOWN UNKNOWNS

Although quick to embrace the economic potential of nanotechnologies, governmental control strategies confronts a number of intractable difficulties. An amalgam of scientific, technical, commercial and regulatory complexities conspires to render regulation of the science and the technology an intricate task. Nanotechnologies enable the manufacture of entirely new synthetic substances that are markedly different in atomic structure from naturally occurring substances – and whose effects on humans and the environment are therefore completely unknown. Most nanomaterials meanwhile represent nanoscale versions of well-known substances like iron or silver. The behavior of a substance can however change radically when it falls below certain size thresholds: a particle of 10 nanometers *can* behave completely different from the exact same substance at 100 nanometers. Unlike traditional bulk chemicals, whose effects varies as a result of molecular structure, mass and concentration levels, size dependent properties render attempts to evaluate, model and predict the toxicity and behavior of nanoscale materials far more complicated. Familiar substances like iron that are known to be harmless can become toxic solely on the basis of their small size. Regulators usually rely on their knowledge of familiar chemicals to extrapolate and predict the properties of new and unfamiliar substances. Because even very small differences, such as a coating, can critically alter a nanomaterial's effects in biological systems (SRU 2011: 5f.), extrapolations from known materials, which could assist regulators determine and prioritize the need for safety testing, remain as a consequence highly unreliable. Although the body of knowledge is growing, an understanding of how the properties of nanomaterials determine their biological effects remains elusive; and, the perplexing bottom line is that there is currently no method to predict which nanomaterials will produce a toxic response and which will not (Marchant, Sylvester and Abbott 2008: 44; 2010).

A further complication stems from a lack of appropriate instruments to monitor and study the behavior of nanomaterials. Most of the tools designed for the nanoscale were driven by the needs of the semiconductor industry – an industry whose products are created in a very dry, ultra clean and high vacuum environment. 57 percent of all industrial R&D is however spent on applications that work in a liquid medium from gasoline over lubricants to blood. In a vacuum, liquids boil off at room temperature and most detection tools are consequently useless for studying how these materials behave in other media like soil, water and air. Without the tools to describe, specify,

characterize and measure nanomaterials, state authorities are unable to define and enforce protective standards. Consider exposure limits for carbon nanotubes as an illustration: the U.S. National Institute for Occupational Health and Safety recommends an exposure threshold of seven micro grams per cubic meter. Is exposure below this level safe? Frankly, we do not know. But current detection techniques cannot measure CNTs below this level.[1] Technical impairments and engineering problems then obstruct attempts to discover, study, and manage the potential adverse effects of nanomaterials.

The risk management challenges arising from the paucity of scientific data and the lack of appropriate instrumentation are at the same time exacerbated by the speed of development within the field and its heterogeneous nature. Nanomaterials are manufactured and used by businesses in a wide variety of market segments and product sectors from cosmetics to construction. Many nanomaterials are developed in a decentralized fashion, with a significant percentage of production coming from small, dispersed university spin-offs and startups. The processes used in the production of nanomaterials as well as their uses in the manufacture of other products are further tremendously diverse. As a result, collecting data on which materials are being produced, ascertaining how and for what applications these materials are used, and developing an efficient enforcement strategy, is hampered by the sheer number and diversity of facilities involved (Florini *et al.* 2006: 45).

Framing nanotechnologies for regulatory purposes has finally created its own set of problems. Statutory regulations require – among other things – clear definitions of what is to be regulated and understandable compliance requirements (Marchant, Sylvester and Abbott 2010: 124f.). But finding adequate language has proven difficult: there is for example no internationally agreed definition of the term 'nanomaterial' with standardization bodies, scientific institutions, authorities and private organization each advancing their own definitions. Efforts to establish common terminology, nomenclature, protocols for toxicity testing and reference materials are likewise in their infancy. State authorities are in consequence unsure of how to specify the obligations of manufacturers to test and obtain safety-related information for their materials. Should regulators for example distinguish among nanoparticles that are engineered and incidental, soluble and insoluble, free and embedded, and so on? Do nanomaterials have one, two or three dimensions at a scale below 100, 200 or 300 nanometers? How relevant are structure, composition, shape and other properties for regulatory purposes? These and similar questions

[1] Interview, Washington, D.C., April 23, 2012.

have yet to be answered conclusively (Jaspers 2010: 271f.). Given the sheer number of nanomaterials that are being researched, developed and manufactured as well as the range of parameters – size, shape, composition, coating, reactivity, surface area and chemistry – that might influence their behavior and properties, governmental control strategies are in short confronted with a task of daunting proportions.

CONTROLLING (NANO) CHEMICAL HAZARDS

Most of the complexities frustrating the design of effective control policies are rooted in the same problem: information – or rather a lack thereof. Whether looking to formulate a generic policy for nanomaterials, decide on an appropriate safety standard, or assess the risk of a specific nanomaterial, state authorities require vast amounts of information. Consider, for example, a regulator seeking to estimate the risks of a given nanomaterial: to do so, the regulator must proceed in three steps – hazard identification, dose-response assessment, and exposure quantification – each demanding separate data inputs. Our regulator must first identify the possible hazards of the nanomaterial in question by evaluating the qualitative evidence of harm. Based on this assessment, she must secondly determine the relationship between dosage and the probability and severity of an effect. Finally, our regulator must estimate the amounts or concentrations to which individuals or the environment is or may be exposed. Information about the nanomaterial's intended use and fate is therefore as important as knowledge about its intrinsic properties, since exposure is a precondition for any harm to occur. If there is no exposure, there is no risk.

But our regulator's information needs do not end here: to control the risks of the material, she must further consider questions of technology and cost. The regulator must ask which responses are likely to be effective, what degree of improvement each is likely to accomplish, which control technologies are available, and what the improvement will cost (Applegate 1991; Esty 2004). To regulate nanomaterials, state authorities must in other words consider four basic kinds of information: they need to know about the nature and magnitude of any harmful activities or products, including the probability of such harm (risk assessment); they need information to decide how to allocate limited resources among identified hazards (priority setting); and identify and evaluate possible responses (standard setting). Finally, regulators need information to enforce their chosen response (Applegate 1991; Coglianese, Zeckhauser and Parson 2004). But for most nanomaterials, this information is not readily available. And, at present, regulators have neither the resources nor the technical tools and regulatory instruments to effectively acquire the

information they need. Consider the problems of data generation through government-sponsored safety studies.

Our regulator from above may well decide that the available evidence for the risks of say nano-silver (or the lack thereof) warrants further research. Bracketing budget restraints and the significant costs of safety testing,[2] she might decide to draw on existing in-house expertise to conduct this research. Or she might commandeer the expertise of academic researchers, independent consultants, or even nongovernmental organizations. If the information she seeks is of a general nature – for example the effects of nano-silver on health – this might be worthwhile. But studying the properties and behaviors of nano-silver would not tell her much about levels of exposure to – and therefore risks of – nano-silver. Unless our regulator can acquire information about use patterns, production processes, exposure pathways and endpoints, she will be unable to define a tolerable risk threshold for nano-silver (Meili and Widmer 2010: 447); and she will consequently struggle to decide on the best course of action. Internal agency experts or outside consultants will be of little help. Characterizing the risks of nano-silver and other nanomaterials will instead to a wide extent depend on accessing information held by industry.

Nor can our regulator rely on traditional regulatory instruments to gather the information she requires. Take something as apparently simple as tracking the use of nano-silver in industry: most chemical management frameworks define standards and exemptions from them based on molecular identity and mass – not particle size. Only changes in quantity, concentration or chemical structure, not in size or shape, will trigger identification, notification and classification requirements (Ludlow 2008). Unless the nanoscale form of a substance constitutes a change in chemical identity, nanomaterials will in most cases be classified as the same substance in bulk form. Until specific provisions are put in place, nano-silver will be regulated as silver; nano-iron as iron and so forth. Manufacturers and users are not required to register and label their nanoscale materials as such and much less undertake additional safety testing – and nanomaterials can in consequence enter the market relatively unrestrained and unnoticed. State agencies can only demand disclosure and production of information, when they are so authorized by their political masters, and for nanotechnologies they lack this authority. Our regulator is in other words unable to mandate disclosure of which materials are being produced, how and for what applications (Florini *et al.* 2006: 45).

[2] Jae-Young Choi and colleagues (2009) for example estimate that the costs of testing existing nanomaterials on the U.S. market will range from US$ 249 million to US$ 1.18 billion.

Most of the information needed to regulate the risks of nanomaterials is thus unavailable or inaccessible to state authorities – either because the scientific knowledge to support hazard identification and dose-response assessment simply does not exists or because the scientific, technical and professional expertise needed to decide among alternative control measures is beyond the grasp of agency officials and experts. Or because information on use patterns and product details relevant to exposure assessment is widely dispersed among manufacturers and users. Compiling data and gathering knowledge sufficient to develop a systematic risk management approach to the nanomaterials currently on the market is likely to overwhelm available risk management resources for most state authorities – and by the time it is done, new generations of nanomaterials will already have entered the market, creating new risk uncertainties (Marchant, Sylvester and Abbott 2008: 44).

While the amalgam of scientific, technical, commercial and regulatory uncertainty certainly complicates attempts to gather information, a lack of reliable information is not a problem unique to nanomaterials: a common theme of much writing on toxic substance regulation is thus "the dearth of scientific [and basic] information available to assess the impact of industrial activities on public health and the environment." (Wagner 2004: 1619) Toxic substance control demands that state authorities produce, collect and process relevant information as evidence of toxicity and exposure continues to surface and accumulate. As new hazards are revealed, agencies must update and reevaluate their safety assessments or control policies. But in many cases the evidence of harm is sketchy, based on studies of variable design and quality, and subject to interpretation according to changing assumptions and analytic judgments that are beyond the grasp of the untutored. The effectiveness and cost of alternative control measures are difficult to estimate, and their appropriate design and application often depend on the knowledge of specialists (Brickman, Jasanoff and Ilgen 1985: 157f). Chemicals regulation is thus a continuous, resource-intensive and time-consuming process – one which requires state authorities to rely on industry to provide the bulk of the information they need.

State bureaucrats are usually poorly positioned to gather information about business operations, or at least to gather it cheaply. Even where they try, it is almost always more expensive and time consuming, since chemicals manufacturers and users have significant advantages in cumulative experience, technical skills, access to data, and research capacity, not to mention the fact that they own the production process (Coglianese, Zeckhauser and Parson 2004: 287). Bureaucracies are created to organize expertise and manage information needed to implement state policies. But their expertise tends to be general, say on the material properties of nano-silver and its impacts on health; and, while state bureaucrats can collect an impressive array

of data about the policies they govern, it tends to be of a standardized and easily observable nature (Scott 1998; Culpepper 2003: 194). Yet general scientific expertise and statistical data is insufficient, when state agencies must decide how to regulate suspect chemicals or particular industry practices. State authorities instead need detailed and accurate information about business operations to understand the scope of the regulatory problems they cause – and how to craft effective solutions to them. But this information cannot be supplied without the assistance of chemicals manufacturers and users, or at least only with difficulty and at great cost. Quoting two German officials, Volker Schneider (1985: 180) writes:

> "Chemicals control policy […] depends to a large degree on the cooperation between government, industry […] and science. Thus, the environmental assessment of chemicals … requires a good deal of scientific, technological and economic information, which the administration does not have, and can only get from those concerned. Since the provision of appropriate reliable information from industry and science can be secured only to a limited extent through compulsion, cooperative relations between government, industry and science are necessary conditions for the guarantee of a sufficient supply of information."

The best sources of information about nanoscale and macroscale chemicals, industry practices and processes, the costs of mitigation, or the feasibility of different control technologies are in short the very companies, authorities are looking to regulate (Coglianese, Zeckhauser and Parson 2004: 278). Governmental appeals for collaboration, voluntary disclosure and the emphasis on the strategic value of partnerships with industry should be seen in this light.

THE CHEMICAL INDUSTRY AND THE MANUFACTURE OF UNCERTAINTY

Manufacturers and users of chemicals ordinarily are in the best position to cheaply and accurately provide or obtain toxicity and exposure data, since they have the greatest familiarity with their products' characteristics and the occasions for exposure to them. Companies learn through their own testing and analysis, from reports of complaints by customers or workers, or simply based on their superior understanding of their products and processes (Applegate 1991: 299). Product liability laws and the prospect of consumer rejection of dangerous chemicals likewise create strong incentives for industry to learn as much as possible about their products. Companies in fact almost always know much more than regulators about the risks associated with their substances, production technologies and manufacturing processes (Grant, Paterson and Whitston 1988: 60f.; Wagner 2004: 1642). Although they may have an interest in sharing favorable, self-serving information, chemicals manufacturers and industrial users have few incentives to produce, disclose or otherwise assist in the acquisition of data about possible adverse effects.

Concerns for intellectual property, confidentiality issues, regulatory liabilities and a desire to avoid negative publicity should hazards be discovered at a later stage result in overwhelming incentives to minimize transparency about harmful substances or activities (Lyndon 1989; McGarity and Wagner 2008: 28f.).

Virtually no market benefits accrue to companies, which publish data on the safety of their chemicals. Safety research cannot easily be validated or compared, and consumers and investors are unlikely to make purchasing or investment decisions based on a manufacturer's self-serving statements about safety. Yet, while disclosure of test data seldom provides a clear market signal, a negative result is almost always definitive: when a substance does cause cancer in laboratory animals, ambiguities concerning how those results should be extrapolated to humans does not substantially diminish the adverse publicity associated with the discovery of its harmful effects (Wagner 2004: 1634ff.). Toxicity and exposure are negative features of chemicals and a nanomaterial's latent toxic effects are hardly a point in its favor in the market. But even disclosure of test data acquitting a chemical of suspicion could cause significant economic harm, since it might provide important assistance to knowledgeable competitors. An inability to protect confidential information rapidly diminishes the returns from innovation, and alerting competitors to market strategies, trade secrets and plans for long-term profitability could prove disastrous.

Legal safeguards allow manufacturers to impede public access to a large body of information regarding their manufacturing processes, test data and products. But companies also have incentives to withhold or discredit information that could help governments regulate. Regulation and enforcement tend to increase in lockstep with the availability of information on harmful effects: whereas no information usually means no regulation, a solid body of uncontested, adverse information will almost certainly lead to intrusive regulation or perhaps a ban on the activity or substance in question. Industry in consequence has strong incentives to keep incriminating information tightly under wraps – or to release such information only slowly (Coglianese 2007). Since much of the information needed to design, enforce and justify regulatory action lies within the particular knowledge of industry, manufacturers and users of chemicals are however also superbly well-positioned to influence the decisions and outcomes of toxic substance control.

When information is sorely incomplete, controverted, or effectively unobtainable, state authorities are often unable to decide how to intervene against suspect substance or industry practices. Even under a precautionary standard, uncertainty and a lack of knowledge will act to delay or impede a regulatory response. Since uncertainty can mitigate or avoid the costs of regulation altogether, industry faces compelling reasons to manufacture uncertainty about

substances and their adverse effects (Lyndon 1989: 1820). Simply withholding damaging information and publicizing only favorable information can allow companies to present a misleadingly positive account of their products and processes – and hence offset incriminating information produced by others. Or companies can use their control of key information to produce inflated estimates to suggest that the costs of a new regulation will be higher than anticipated or that its benefits will be lower. Unless outsiders can gain access to 'inside information', biased cost estimates will effectively stand unchallenged. Submitting volumes of highly specific and very detailed technical data can likewise permit companies to bury damaging information in a mountain of 'irrelevant' material with the effect of slowing down the control process to a virtual standstill (Wagner 2010). Overloading an agency with more information than it can absorb is thus but an extension of a conscious strategy to keep regulators in the dark.

If independent research does find evidence of harm, challenges to its methodology, data interpretation, sampling or review processes can be used to question the results in the eyes of officials. The simple fact that a study has been subjected to lengthy and credibly-sounding attack is often sufficient to impair its perceived reliability. And portraying research as 'fatally flawed' or 'tentative' can serve to generate pressure on decision-makers to discount it (McGarity and Wagner 2008: 38ff.). More elaborate efforts to manufacture uncertainty entail investments in 'counter-research' carefully tweaked to produce results more favorable to the manufacturer's interests: keeping doses low, shortening the duration of an experiment, using animals that are resistant to cancer and many other clever tricks have in the past been employed to produce results that make chemicals seem less dangerous than they are (Collins 2010: 116; Fagin, Lavelle and the Center for Public Integrity 1996). From industry's superior information, knowledge and expertise therefore flows a significant influence over the course of chemical control policy. While nanotechnologies *are* recognized to demand a regulatory response, companies might nonetheless diminish its adverse effects, simply by minimizing the amount or credibility of information that could indicate cause for concern or justify more intrusive regulations. The pervasive information deficiencies confronting state agencies in other words present unique opportunities to influence how governments will decide to govern the technology.

BUSINESS INTERESTS AND NANOTECH REGULATION

Debate on the nature of an appropriate response to nanotechnologies has waged for the better part of a decade. Manufactures and users of nanomaterials obviously have much riding on the outcome of this debate. Statutory regulations might increase business costs, erect barriers to

market entry or result in lower or changing patterns of innovation – the lifeblood of the industry. 'Business' is however not a homogenous group, but represent rather a number of competing and often conflicting interests (Hart 2004). Although industry leaders thus have struck a harmonious cord in rejecting 'premature' regulation, they do not necessarily see eye-to-eye on how the state should govern the technology. The nanotech industry is not monolithic, and questions of oversight and regulation are viewed distinctly by corporate decision-makers according to factors ranging from business resources over market location and orientation to research and development strategies. Given the fragmented and complex industry structure, state intervention will impact very differently on members of the industry – and their regulatory stakes consequently differ.

Despite the heterogeneous nature of the industry, two distinct types of 'nanobusinesses' are emerging: the large and the small. With their different resources and dispositions, large and small companies have distinct and often diverging interests (Traxler 2007). While statutory controls on nanomaterials and their risks will infringe on the interests of all companies, compliance costs will not be equally distributed across large and small manufacturers. Consider for example the implications of mandatory testing requirements: safety testing raises the costs of bringing new products to market and may discourage companies from sinking funds into risky new ventures. Because they lack the economic resources and experience to mount sophisticated screening programs, testing will however be disproportionately burdensome for small companies. Testing obligations may in contrast work to the advantage of large corporations: small companies are frequently unable to understand and cope with statutory requirements (Ashford and Heaton 1983), and large corporations might therefore wish to promote mandatory testing as an instrument to undermine the profitability of startups, allowing incumbents to buy up their patents and intellectual property as they crash.

Large manufacturers nonetheless have little reason to welcome extended testing requirements: first, expected returns in small-volume chemicals are rarely sufficient to offset the cost of testing (Schulze 1985). Because most nanomaterials still – at best – are produced in kilos not tones, new testing obligations will encroach on the profit margins of large and small manufacturers alike. Second, since rival products made without nanoscale materials would not be subject to similar requirements, even where they present comparable or perhaps greater risks, testing obligations would place nanomaterials at a distinct commercial disadvantage (Marchant, Sylvester and Abbott 2010: 131); and an obligation to test all novel nanomaterials and products might therefore serve to thwart the industry's long-term economic prospects. Although their rationales may differ,

companies of all sizes thus face compelling reasons to resist statutory obligations that could result in increased cost, delays on market entry, and so on.

While overly zealous environmental, health and safety regulations might indeed bring the nanotech innovation boost to an abrupt end (Lin 2007: 112), the current mix of scientific and regulatory uncertainty also acts as important barriers to successful commercialization (OECD 2010). When there is a clear legal framework associated with a given range of economic activities, businesses are better able to identify and quantify commercial risk. Statutory regulations can of course increase business costs. But they also serve as guidance to expected behavior and so help build confidence in an industry – especially an industry that may involve significant, but uncertain risks (Paddock 2010: 183). In a stable and hence more predictable regulatory environment, investors and lenders are more willing to offer financial support, and insurers are more inclined to cover potential liabilities. The inconclusive status of nanomaterials under extant statutes and regulations therefore presents industry with other opportunities and predicaments than a mere desire to minimize state interference.

Whether the issue is patenting or testing of novel nanomaterials, a predictable regulatory response will facilitate access to venture capital as well as reduce insurance and other operating costs; and, a stable regulatory environment will thus be vital to the success and survival of startups and other small companies. Reflecting on the issue of testing, an industry observer noted: "[Small companies] really did want testing. What they don't want is uncertainty. They don't want a regulatory wasteland. And they don't want testing that doesn't work. So, they don't want unfair and burdensome testing. […] Early in the game, they want to know what the testing [requirements will be]."[3] But large manufacturers likewise face high stakes in a clear set of regulations governing their products and activities. Although their political resources and strong legal teams allow large corporations to navigate the control process, they also need regulatory clarity to minimize risks of patent litigation or avoid undertaking expensive and long-term R&D for applications, which may later be banned (Davies 1983; OECD 2010: 89).

The uncertain legal status of nanomaterials further leaves industry liable for damages in the event that manufacturing processes or products are later discovered to present dangers to humans or the environment. Because the science is continuously evolving there is as Amy Fink (2007: 23) notes a possibility that "issues arising out of nanotechnology will not become apparent until years or even decades after such nanoparticles have been dispersed. This could result in a

[3] Interview, Washington, D.C., April 17, 2012.

flood of 'long tail' claims." For small startups, prospects of long-term health effects need perhaps not figure prominently among their day-to-day concerns: by the time hazards can be established for their applications, they may long have ceased operations or been acquired by other companies.[4] As the market consolidates, then, incumbents – and their financial stakeholders – could be forced to foot the bill of toxic legacies emerging from their own products or from their acquisitions. Uncertain of how to quantify or cost liability, insurers have for example been among the first stakeholders to urge caution (See *e.g.* Swiss Re 2004; Gen Re 2004; Allianz 2005; Lloyds 2007). Sparse exposure and toxicology research, a lack of nano-related accident history, and the breadth of nanotech applications have insurers concerned that "[t]he examples of accidents and individual claims frequently mentioned in connection with nanotechnology are only the tip of the iceberg." (Swiss Re 2004: 39) Unless and until measures are undertaken to address such uncertainties, the insurance industry might decide to price premiums conservatively, and be selective in the types of risks they insure against (Guy Carpenter 2006) – an approach illustrated by Continental Western Group's 2008 decision to refuse coverage for clients involved with carbon nanotubes. While this policy was later retracted, limits on insurance coverage would create major impediments for companies engaged in nanotechnology research, with new ventures either being put off or decided against completely. Without clear statutory guidelines, companies however remain uncertain about their obligations, leaving them – as well as their investors and insurers – guessing about their eventual degree of liability exposure (Dana 2010; DeVries, Gotting and Liebfarth. 2010).

Consumers and business partners meanwhile prefer to buy tested and safe product, but will tend to shy away from products with uncertain effects or unknown risks. Yet, until effective risk management methods, guidelines and instrumentation are developed, companies cannot effectively demonstrate the safety of their products. This lack of agreed standards to facilitate communications among manufacturers and their customers on quality and safety issues is consequently viewed as one of the major barriers to successful commercialization (OECD 2010). The market however will produce neither instruments nor guidance, and companies must instead look to the state to provide the necessary risk management infrastructure. The slowly evolving regulatory environment and the absence of an unequivocal statutory response at the same time readily feeds into public perceptions of government inaction in the face of unknown hazards; and nanobusinesses, especially large companies with conspicuous brands, are consequently vulnerable

[4] Nonetheless, startups that ignore possible health and safety implications will discover that interest in their novel materials and processes – no matter how promising – is not as keen as they had hoped.

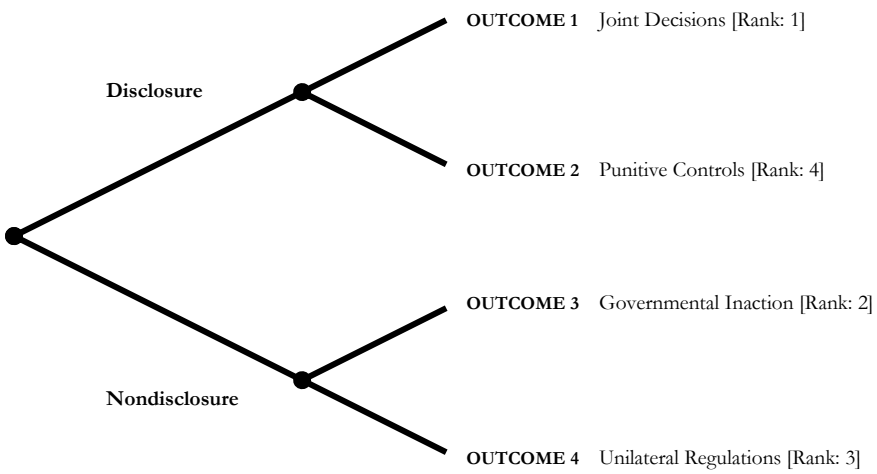
to consumer boycotts and visceral market reactions. Reservations on part of financial stakeholders, combined with the potential for public backlash, could eventually frighten off business partners and downstream users, severely reducing the industry's economic prospects. Several global food companies, including once market leaders such as American Kraft Foods, have for instance already taken measures to disassociate their products and brands from nanotechnology. Mounting public hostility to nanotech could ultimately compel politicians to entrench 'irrational' or 'uninformed' sentiment into official policy, cut public funding, erect costly test barriers or even introduce a moratorium on further development (Sylvester, Abbott and Marchant 2009: 169). How states decide to govern the uncertain promise and unknown risks of nanomaterials will in large measure determine the long-term commercial viability of nanotechnologies and hence shape the fortunes of nanobusinesses – be they large or small. While regulations might come at a price to flexibility, a clear legal environment also promises significant benefits in terms of regulatory certainty, stakeholder confidence and business predictability, which cannot simply be ignored.

THE RISKY LURE OF DISCLOSURE

Although the regulatory process has remained mired in a search for appropriate control mechanisms, the question facing policy-makers, regulators and industry was never *whether* the state should intervene to guarantee public health and safety, but *how*. If reducing the scope of state interference was their only or even primary concern, manufactures and users of nanomaterials might be best advised to limit available information about their operations. In the current situation, however, regulatory uncertainty complicates the commercial environment for companies and impedes the market performance of nanotechnologies (OECD 2010). While over-regulation thus indeed may be the fear of some, industry at large nonetheless has an interest in promoting outcomes that could translate into a long-term stable and favorable business environment. And given their superior information, knowledge and expertise, companies will be well-positioned to influence how the state decides to intervene to ensure human health and environmental integrity.

With regulators scrambling at the complexities of scientific uncertainty, new information can exercise a significant impact on regulatory agendas, priorities and policies (Haas 1992). This can work in industry favor, if disclosing information succeeds in convincing state bureaucrats to make decisions that either reduce anticipated costs or increase private benefits. Disclosure and

Figure 2.1 The Risky Lure of Disclosure



cooperation might for instance convince governments to provide financial subsidies for testing of existing nanomaterials or for coordinated research efforts for a particular group of products. Inputs on market conditions or the state of applied science could likewise expedite the drafting of guidance documents, common standards and nomenclature. Or disclosure might simply afford companies opportunities to negotiate control measures that accommodate their views on mitigation techniques and costs. Once enshrined in regulation, a negotiated standard might promote inertia and regulatory 'lock-in', hence reducing the likelihood of future more rigorous regulations. Information and expertise are key resources for influencing the design of regulatory policies and research investments intended to develop new risk management methods. Cooperation with state authorities could therefore allow companies to mold the very scientific basis, technical tools, test protocols, procedures and nomenclature regulators must employ to craft and justify future decisions and actions. Disclosure might in other words allow companies to capture private benefits or reduce compliance costs under the current rules of the game; and over the longer term to bend those rules to serve their interests.

Whether the lure of influence will indeed be sufficient to induce companies to disclose information depends of course on the expected consequences of cooperation. Schematically, when evaluating their choice of disclosure or nondisclosure, companies must anticipate one of four possible 'outcomes' (See figure 2.1). Viewed from industry's perspective, we may refer to these as: joint decisions (OUTCOME 1); punitive controls (OUTCOME 2); governmental inaction (OUTCOME 3); and, unilateral regulations (OUTCOME 4). We can assume that industry will rank these

outcomes as follows. With a regulatory response looming on the horizon, companies will prefer to shape that response to their strategic advantage (OUTCOME 1). Companies may in consequence be inclined to accept some degree of constraint on their operations in exchange for state policies that could help stabilize the business environment, limit liability exposure, prevent market failures and promote regulatory lock-in on outcomes favorable to their interests (Shaffer 2010: 65). With the promise of influence, companies may therefore readily volunteer information, share their expertise and actively assist regulators in the acquisition of new data. Cooperation in short serves industry's interests as well as regulators' needs. But disclosure is also a dangerous course for industry: while regulators certainly appreciate information volunteered by industry, they may value the information differently than originally anticipated. Seemingly unimportant data could in fact be just the information needed to impose stringent new restrictions on industry products or practices. Unless companies can trust regulators to respect their interests, cooperation is a risky strategy (OUTCOME 2).

Maintaining silence, *i.e.* nondisclosure, on the other hand represents the conservative gambit. Manufacturers and users of nanomaterials are of course not the only source of information, and they certainly do not have a monopoly on expertise. State bureaucrats have their own sources of information; and while information might currently be either under-supplied or inaccessible, the knowledge about and understandings of potential risks is steadily accumulating. Regulators may therefore eventually feel convinced that specific restrictions, control policies or legislative amendments are required and justified – regardless of the degree of industry disclosure (OUTCOME 4). While nondisclosure does not preclude or prevent state intervention, uncertainty and a lack of knowledge usually act to delay a regulatory response. Regulators may moreover find it difficult to justify comprehensive regulatory action, especially if industry can find ways to discredit or question the credibility of existing information (Lyndon 1989: 1819f.). Ultimately, industry resistance could prove sufficient to reverse the tide of regulatory action – but it could also fail. Between unilateral regulations and punitive controls industry is thus caught between a rock and a hard place. Because nondisclosure might force state authorities to settle on less intrusive controls, unilateral regulations should nonetheless be preferable to companies intend on minimizing regulation's adverse effect.[5]

Better still would of course be governmental inaction (OUTCOME 3). Given the pervasive information deficiencies, regulators might find it altogether impossible to justify regulatory

[5] Not to mention that nondisclosure will shelter companies from breaches of confidentiality, competitive disadvantages, increases in liability exposure, and so.

action; and they may therefore wish to limit state intervention to minor, cosmetic adjustments to extant regulations or broad statements on their relevance to nanotechnologies. With the associated degree of business predictability, the benefits to companies cannot be dismissed. But governmental inaction also fails to address the roots of some of the persistent challenges in the current commercial environment. Governmental inaction offers limited guidance to companies looking to demonstrate the properties, quality and safety of their novel products and applications; nor will inaction help establish procedures needed to credibly communicate such information to consumers and business partners in the value-chain. Since moreover minor, cosmetic changes to extant regulations can be implemented with relative ease, they can just as easily be undone. Failure to lock-in a favorable outcome consequently robs companies of a solid safeguard against future adverse regulations should new incriminating evidence come to surface. While governmental inaction thus promises companies freedom to operate in the short term, it may well fail to translate into a long term, favorable business environment.

We can in short assume that companies will prefer regulations decided through mutual agreement to governmental inaction, which in turn is preferred to unilateral regulations. Avoiding the debilitating impacts of punitive controls should nonetheless dominate corporate risk-benefit calculations. Whether industry decides on a strategy of disclosure or nondisclosure will however ultimately depend on what companies can expect their regulatory adversaries to do.

Regulators for their part will prefer that industry discloses, rather than withholds or distorts, needed information. And they may therefore be willing to pursue policies that accommodate the interests of industry. Establishing upfront how regulators will react should industry decide to disclose or withhold information is nonetheless somewhat tricky. Nanotech confronts policy-makers and risk managers with all the characteristics of a classic policy dilemma: while on the one hand seeking to encourage the technology's economic and societal benefits, governments must balance this desire against the need to ensure human health, public safety and environmental integrity on the other (Hodge, Bowman and Ludlow 2007: 6). Governments would undoubtedly prefer to land the regulatory process on an outcome that both eliminates, or at least minimizes possible risks *and* ensures a favorable business environment. An outcome that accomplishes neither, in contrast, represents a scenario that governments understandably are determined to avoid. And, in some situations, crafting effective risk management policies that do not overburden industry with new obligations may indeed prove unproblematic. Often, however, state policy will be unable to reconcile these twin goals; and in such cases regulators must decide how best to mitigate risks to human health and the environment without compromising industry's ability to innovate and compete.

Hence, whether disclosure will result in joint decisions or whether it will compel regulators to respond with punitive controls is a function of how state authorities trade off safety for competitiveness, when their policies can accomplish one, but not both objectives simultaneously. How state bureaucracies rank outcomes that achieve one goal at the expense of the other is contingent both upon organizational attributes, such as *e.g.* their statutory mandates, their resources, internal power structures and so on, as well as the political environment within which they operate. Agencies staffed predominantly by industrial hygienists, toxicologists or other specialists are likely to approach such trade-offs in a different manner than those dominated by lawyers, economists or other generalists. Statutory mandates insisting on elaborate cost-benefit balancing likewise conditions different trade-offs than statutes stipulating a strict application of the precautionary principle. Reactions by independent regulators will meanwhile differ from state agencies that must anticipate frequent interference from elected politicians, while variations in the capacity of organized interests to pressure an agency dictate yet again different trade-offs (Wilson 1980; 1989). And so forth. Because the agencies charged with oversight of nanotech as well as the political circumstances they must navigate are so tremendously diverse, an unequivocal answer to when state actors will prefer outcomes that allow industry freedom to operate at the expense of human health and environmental integrity – and *vice versa* – is hard to come by. Given the variance of contexts and state actors, it is in other words unwise to impute to regulators rigid preferences for one goal over other (Frieden 1999: 61ff.); and we are instead better served by leaving this as a question to be answered by the empirical record.

REGULATORY POLITICS AND THE PROBLEM OF COMMITMENTS

To succeed in regulation of complex social and economic processes, states require accurate information about the possible and actual consequences of their policies. Left to their own devices, state authorities however frequently find it impedingly costly, if not impossible, to gather the information they need – and they may therefore wish to turn to business or other private actors as a cheaper and more reliable alternative source of information. State policies thus often depend on the behavior and cooperation of individuals, groups and industries to meet their objectives. But companies must be wary of sharing information about their operations with state actors, who under a range of unpredictable influences may decide to use the information against business (Hall and Soskice 2001: 47). Fear of state interference in other words cautions against supplying truthful information. Clearly, it is not always in the interests of state actors to defect from a cooperative agreement: by striking a bargain with business, states can craft and implement

more efficient policies. But efficiency alone is insufficient to guarantee that state actors will abstain from reneging on an agreement (North and Weingast 1989: 806; Morrow 1999: 96). State preferences change over time, and while state actors may wish to encourage cooperation with business, their incentives after the fact are not always compatible with maintaining an agreement (Schelling 1956: 299; Shepsle 1991: 247f.). Unless short-term incentives to alter agreed policies can be eliminated, business has reasons to doubt whether or not state actors intend to honor their promises. Business will in short only cooperate with state actors, if their commitment to abide by an agreement is credible.

When states cannot rely on coercion to implement their policies, a lack of credibility becomes problematic: if future policy changes can be anticipated, social and economic actors may fail to react and adapt as intended, thus preventing the policy from attaining its objectives. Since the information needed to design and enforce effective chemical control policies only to a limited degree can be secured through compulsion (Schneider 1985: 180), the capacity of state bureaucrats to make credible commitments will influence whether companies will decide to disclose, bias or conceal information. Companies will only volunteer information to state bureaucrats if they are confident that the information will not be used to the detriment of their interests. Where such expectations are not well-founded, companies must in contrast remain vigilant to possible ulterior motives: nondisclosure is rational, if companies have reasons to suspect concealed agendas. When deciding between a course of disclosure or nondisclosure, companies must in other words attempt first to anticipate how regulators will evaluate the available body of knowledge; second how they can be expected to act on that knowledge; and finally what impact new information will have on their decision-making. We must therefore look to the institutional mechanisms that allow state bureaucrats to convince companies that they can be trusted with sensitive information.

To understand the impact of institutions on business responses, we need to examine their links to the risk-benefit calculations of companies. Institutions enter strategic calculations by providing information about the choices of others. Because they define the range of available actions, institutions provide a rational basis for formulating expectations about how other are likely to act (Knight 1992: 55ff.; Lake and Powell 1999: 8f.). Institutions can therefore mitigate commitment problems by reducing uncertainty about future behavior (North 1990). The institutional configuration of national chemical control regimes thus structure business expectations about the likely behavior and responses of state bureaucrats: formal and informal institutions transmit information on the possible intentions, priorities and designs of regulators.

And this information assists companies formulate strategies to anticipate regulatory developments, given the probable actions of their regulatory adversaries.

Companies draw on two kinds of information to predict the behavior of state bureaucrats: on the one hand, companies use their understanding of how formal institutions and their operating procedures structure the regulatory process and its possible outcomes – and importantly how the control process can be influenced through different strategies. Because they define what regulators can and must do, overarching legal and institutional relationships inform expectations about likely response to new information, and how withholding or disclosing information might influence that response. On the other hand, repeated historical experience builds up a set of common expectations that allow companies to anticipate how regulators might react to new information. Knowledge about past behavior serves as a guide to predict how regulators will respond in the future (Knight 1992: 77-80). Companies rely on both kinds of information to gauge the credibility of bureaucratic commitment. Countries however differ in their institutions and processes of chemical control; and companies are thus presented with different kinds and amounts of information about the probable behavior of state bureaucrats. I argue that two features in particular of national chemical control regimes are responsible for the capacity to commit to cooperation with industry: the regulatory powers of state bureaucrats and their reliance on advisory bodies in the formulation and implementation of chemical safety policies.

COMMITMENTS AND BUREAUCRATIC AUTONOMY

The varieties of capitalism literature suggests that the credibility of governmental commitments is systematically linked to their policy-making powers. Governments operate within distinct constitutional and political environments that dictate when and how they can intervene in the affairs of social and economic actors. Institutional constraints on their policy-making powers thus determine the capacity of governments to commit to a set of stable and predictable policies (Wood 2001; Gourevitch and Shinn 2005). Fragmentation of political authority decreases the capacity to initiate policy change at whim, without first consulting and placating multiple veto players. In separation of powers systems, for example, precisely because the legal status quo is so difficult to change, any political agreement that is embedded in legislation will be durable, and everybody knows it. Once a law is passed, the capacity to renege on an agreement – by passing a new law that reverses it – is drastically diminished (Moe 1990: 242). Dispersion of political authority therefore promotes the stability and predictability of state policies. Commitment problems will in contrast be especially pronounced in political regimes that vests authority firmly

in the hands of the executive. Concentration of state powers brings uncertainty to the political economy: because governments have the capacity to introduce dramatic reforms at will, social and economic actors must doubt their commitments to pursue a set of stable policies (Wood 2001: 258ff.). Cooperation between state actors and business should in short, as Peter Hall and David Soskice (2001: 48) argue, be more feasible in political systems

> "in which producer groups enjoy substantial structural influence. This structural influence may rest on a number of bases: the authority of producer organizations inside political parties, the entrenchment of neo-corporatist practices in enough spheres of policy-making that defection in one can be punished in another, or policy-making procedures decentralized enough to allow producer groups many points of access and some veto points."

In regulatory politics, however, neither 'structural influence' nor institutional controls on the exercise of authority guarantee the credibility of bureaucratic commitments. Constitutional and political variables do of course impinge on regulatory politics and business strategies; but not necessarily as envisioned by the varieties literature. Comprehensive checks on the decision-making authority of state bureaucrats in fact render cooperation less, not more likely. Political systems differ in how they concentrate or diffuse regulatory powers and authority; and they consequently structure the opportunities for companies to influence regulatory outcomes differently. I argue that the autonomy of state authorities to decide regulatory policies and outcomes, insulated from pressures originating from other branches of government, determines their capacity to commit to cooperation with industry. In what follows, then, I take bureaucratic autonomy to mean an agency's discretionary authority to enact policies that will not be limited or overruled by other political actors.[6] For actors engaged in strategic interactions, the prospect of external intervention alters both their own assessments of the possible outcomes and provides additional information about the probable future behavior of others (Knight 1992: 59f.). We must therefore overtly account for how the powers of other state actors to intervene in regulatory proceedings enter corporate risk-benefit calculations; and how this may discourage or dispose companies to cooperation with state bureaucrats (Ostrom 1990: 190f.).

Establishing generic standards of public safety and environmental integrity is the purview of elected politicians. Toxic substance laws, no matter how specific or detailed however, rarely stipulate what controls should be imposed on particular chemicals. Administrative law-making must instead fill in the gaps left open by the legislature. Applying a general legal mandate to

[6] This definition thus draws on the principal-agent formulation of bureaucratic autonomy as the extent to which agencies are able to implement outcomes that diverge from the preferred policies of their principals, without being prevented *ex ante* or punished *ex post* (See *e.g.* Miller 2005).

classes of chemicals, such as nanomaterials, or to specific cases, such as nano-silver, is a quintessentially administrative task: since legislatures do not and cannot anticipate the full range of regulatory issues at the stage of policy formulation, state authorities usually enjoy considerable discretion to make decisions that are essentially legislative in nature (Brickman, Jasanoff and Ilgen 1985: 74f.; Croley 1998). The constraints placed on bureaucratic decision-making procedures however vary across countries, and there are consequently striking variations in how authorities carry out their regulatory responsibilities. What state bureaucrats can and must do is in large measure determined by the overarching legal and institutional distribution of regulatory authority.

While legislatures in general confer wide discretionary powers on state bureaucracies, they are not equally zealous in their oversight of how those powers are exercised: whereas some parliaments are content to limit scrutiny to the broadest issues of chemical safety policy, others assume an active role in reining in administrative discretion by subjecting agency decisions and policies to intense and protracted investigation. Rigorous oversight and frequent interference from legislators reduce the autonomy of state bureaucrats and shifts the locus of regulatory decision-making towards the legislature. Active review of agency decisions by the courts, special administrative courts or appeal boards likewise decreases bureaucratic autonomy. If administrative decisions can be altered or invalidated by judicial review, state bureaucrats are denied control over the outcome of the regulatory process and the fate of their policies. Since finally chemical safety policy touch upon the responsibilities of several ministries and agencies, oversight by the chief executive and interdepartmental negotiations is necessary to ensure a coordinated governmental response. The tighter the coordination structure, the less able state bureaucrats are to decide regulatory issues, without first consulting and clearing those decisions with other executive actors. Overlapping jurisdictions thus undercut the authority of state bureaucracies. Administrative decisions and policies must in consequence attempt to anticipate the preferences and strategies of other state actors (Kim 2008: 35). And this has implications for industry's choice of disclosure or nondisclosure.

Fragmentation of regulatory powers casts doubts on the credibility of bureaucratic commitments. If administrative decisions and policies can be challenged, revised or overturned at other stages of the regulatory process, companies must question whether regulators will be able to uphold their end of a collaborative bargain. Litigation or political interference motivated by appeals from competing interest can compel state bureaucrats to sudden reversals in policy. But without the autonomy to decide regulatory outcomes, regulators cannot credibly commit to a future course of action. Any cooperative settlement between an agency and the industry it regulates may be vulnerable to political or judicial intervention; and uncertainty regarding the

future behavior of state bureaucrats reduces the value companies attribute to cooperation as benefits are either doubtful or unknown. Concentration of regulatory powers in state bureaucracies can in contrast create the critical impetus for cooperation. As the literature on policy delegation suggests, elected politicians can enhance the stability and predictability of state policies by entrusting regulatory powers to independent authorities. By renouncing their own capacity to influence regulatory decisions, or limiting the scope of judicial review, politicians can reduce uncertainties about the future direction of state policy (Majone 1996; 2001; Miller 2000). Insulated from the political process, state bureaucrats face different incentives – either given their preferences or their statutory mandates, or both – than elected politicians. As they are not subject to the short time horizons imposed by the electoral process, state bureaucrats can pursue their statutory objectives, even when those objectives no longer enjoy popular support (McCubbins, Noll and Weingast 1987; 1989). Limits on political interference or judicial scrutiny may thus convince manufacturers that a commitment to cooperation is credible.

This view of the regulatory process admittedly neglects the many nimble ploys enterprising bureaucrats use to shelter their routines and policies from criticism and external interference. State bureaucrats are not hapless victims of the whims of their political masters, but can and do forge the circumstances under which they operate. Autonomy, Daniel Carpenter (2001: 353) writes, arises "when bureaucrats successfully […] build reputations for their organizations – reputations for efficacy, for uniqueness of service, for moral protection, and for expertise. It occurs, further, when they ground this reputation in a diverse coalition wrought from the multiple networks in which they are engaged." Agencies with a reputation for capacity embedded in an independent power base can compel elected politicians and organized interests to defer to their decisions, change regulatory agendas and preferences, and perhaps even alter the terms of legislative delegation (Carpenter 2001: 15). In the realm of toxic substance control, however, neither organizational reputations nor coalitional politics offer much promise for state bureaucrats looking to buttress their autonomy and expand their regulatory authority.

First, in complex and uncertain policy domains, administrative autonomy depend in large measure on the degree to which bureaucrats can lay claim to valuable expertise as well as their capacity to collect, process and deploy information required to implement their statutory mandates (Atkinson and Coleman 1989: 52). But in the area of chemicals control, bureaucratic claims of privileged knowledge or special expertise are unlikely to stand unchallenged. Gathering, developing and analyzing information remain at the core of control process – one which however requires state authorities to rely on industry to provide the bulk of data needed to regulate suspect chemicals. While state bureaucrats do have their own sources of information and

expertise, manufactures and users of chemicals nonetheless have significant advantages in cumulative experience, technical skills, access to data, and research capacity – advantages that in effect allow companies to cast doubt on the interpretations of law, science and economics advanced by state authorities. Elected politicians for their part are disinclined to defer to administrative decisions that have been subjected to lengthy, loud and compelling criticism; yet because state bureaucrats struggle to build reputations for unique or authoritative expertise, they cannot easily dismiss such criticisms.

Second, the scope for state bureaucrats to assemble broad coalitions of intersecting interests behind their policies is equally limited. A manufacturer might indeed wish to support intervention targeted at its rivals and their products. Or segments of manufacturers and downstream users might have an interest in backing control policies that favor their production processes or mitigation technologies. But on the whole, companies have few incentives to ally with an agency, if this coalition expands its *de facto* autonomy and power to interfere in their affairs. Diffusion of regulatory powers not only leaves state bureaucrats in a tenuous political situation that undercuts the credibility of their commitments. At the same time, overlapping jurisdictions also creates alternative routes for companies and their representatives to influence regulatory outcomes. Taking an agency to court or lobbying Congress are strategies familiar from the American regulatory system. While these tactics may be less readily available to European companies, opportunities for both judicial review and political intervention do exists. More often, however, European companies can defend their interest by appealing for ministerial sponsors to place a break on meddling bureaucrats.

Fragmentation of regulatory powers thus present amble opportunities for companies to deflect or delay regulatory action through indirect means. But as the possibilities to obstruct regulatory decisions proliferate, the incentives to divulge sensitive information to the agencies responsible for regulating their conduct decline. Although dispersion of political authority does promote the stability of governmental policies, institutional constraints on bureaucratic autonomy also detract from the value of maintaining relationships with regulators on congenial terms. Unless industry can hope to capture the agency, companies in short have few reasons to promote its autonomy; rather companies may wish to undermine that autonomy by convincing other state actors to intervene on their behalf against the agency and its decisions. Toxic substance control thus leaves little tactical leeway for state bureaucrats to expand their *de facto* autonomy and authority.

State bureaucrats endowed with the power to decide the direction of regulatory policy in contrast confront companies with a distinct set of risk-benefit calculations: independent state

authorities are not easily swayed by changing political and economic conditions, but focus instead on achieving their statutory obligations and long-term objectives. Since insulation from the political process promotes the stability and predictability of state policies, companies may feel convinced that they can trust state bureaucrats with sensitive information. Absent recourse to the courts, parliaments or other executive actors, companies can on the other hand tread few alternatives paths to influence regulatory outcomes. And they consequently have to win what they can during administrative deliberations. Since information and expertise is the most relevant currency in convincing state bureaucrats, concentration of regulatory powers can therefore create potent incentives for companies to divulge information, if this can be exchanged for influence over administrative decisions and policies.

DELIBERATIVE INSTITUTIONS AND COMMITMENTS

Game theory predicts that actors engaged in repetitive, long-term relationships may develop strategies that reduce the risk of noncooperation in the future. In repeated games, the expected benefit of future cooperation can render commitments self-enforcing (Axelrod 1984). Relationships in a complicated world of unanticipated contingencies are however much more 'dense' than a simple game theoretic analysis would suggest (Scharpf 1990; Sabel 1994). Regulatory problems often have several plausible causes, and they almost always have several potential solutions. Although institutional checks on administrative decision-making procedures do constrain the ability to decide outcomes, state bureaucrats almost always enjoy some scope to influence the direction of regulatory policy. Most toxic substance laws empower state bureaucrats to determine what chemicals to regulate, in what order, by what means, and how stringently. Depending on their specific agendas, priorities and preferences, regulators may thus react remarkably different to evidence of harm. But administrative discretion creates problems for companies attempting to predict how state bureaucrats will react to new information.

For a regulator, the value of any particular piece of information depends on how effectively it fills a gap in the knowledge base and how important that gap is to the regulator's decision-making. Because companies with a hazy picture of the overall puzzle may fail to accurately assess the value and impact of any particular piece of information, the regulator may wish to downplay or obscure the significance of information she seeks from industry (Coglianese, Zeckhauser and Parson 2004: 303). Even a less cunning regulator could inflict real harm on industry, if disclosure compels the regulator to respond urgently to new information, without pause to consider industry inputs on control techniques or costs. Unless companies understand the designs and

intentions of their regulatory adversaries, they cannot predict how requested information might be put to use. And, companies must consequently harbor doubts about the credibility of their commitments. Viewed in game theoretic terms, this translates to problem of uncertain motives and hence a situation of strategic indeterminacy. Without some means of resolving this uncertainty, rational actors are unable to predict how others are likely to respond (Knight 1992: 53; Morrow 1999). Deliberation I argue and the institutions which structure communications among state authorities and industry can overcome such ambiguities and thus bolster the credibility of bureaucratic commitments.

Deliberation is usually meant to refer to a particular form of discussion – and is as such related to other forms of communication such as arguing or bargaining. Communication permits actors to establish the parameters of cooperative agreements, increase trust and hence thwart the expectations of noncooperative game theory. Deliberation however means different things to different people; and, they consequently construe its role and effects in widely different terms. Broadly, we can distinguish among those who understand deliberation as the careful balancing of reasons for or against some decision and those who view it as the act of communicating information through discussion. Here, I advance the latter view of deliberation as discussion. To avoid possible misconceptions, let us however briefly consider the former view and how its proponents understand the role of deliberative processes in regulatory politics.

For proponents of this view, deliberation entails the exercise of practical reason as participants present and substantiate arguments, consider evidence, reflect on matters of mutual interest and attempt to persuade one another. The general claim is that public deliberation produces better decisions: pooling the ideas, views and information of participants and subjecting these ideas, views and information to collective, reasoned deliberation is assumed to yield more innovative, effective and ultimately legitimate decisions, as parties actively and sincerely debate the merits of alternatives in search of the decision that is most consistent with some notion of the common good (Cohen 1998; Rosenberg 2005). Deliberation can lead actors to revise opinions about both facts and values, alter premises, and discover common interests. Disagreements and inconsistencies encourage participants to balance their wants, and this can induce them to modify their choice of means for achieving their ends – and perhaps also to reconsider those ends altogether (Reich 1985: 1635; Croley 1998: 76-82). In the course of deliberative problem-solving, then, interests crystallize not simply because actors only fully recognize their own private interests through deliberation, but also because it is through this process that they come to understand the concerns, goals, and values of others, and how those concerns, goals, and values can be accommodated with their own. Deliberation allows participants to learn how their divergent

views can be reconciled and in the process develop converging definitions of common problems and agreed approaches for dealing with them. Regulatory outcomes are therefore not neatly reducible to the underlying interests of participants, but reflect instead collective judgments about priorities and policies that participants ultimately come to prefer. Through a process of mutual socialization and the consensus it generates, participants may gradually cease to understand themselves as representatives of disparate interests, but rather as representatives of a newly constituted community characterized by mutual learning and trust (Joerges and Neyer 1997: 620; Sabel and Zeitlin 2012). The emergence of collective identities, common values and mutual understandings can hence mitigate commitment problems as members come to share jointly constructed interests.

Whereas deliberation in this tradition is cast as a group hunt for sound, consensus rationales, I instead understand it as a medium for strategic information transmission. In line with the varieties of capitalism literature, I construe deliberation in game theoretic terms as iterative information exchanges that can overcome problems of asymmetrically distributed information or bounded rationality (Hall and Soskice 2001: 11f.; Culpepper 2001). Discussion can have a number of effects on collective decision-making (Fearon 1998); yet, the most relevant in this context relates to the communication of private information. This could be information about how particular actions translate into particular outcomes, information about the consequences of those outcomes, or it could be information about how participants evaluate the consequences associated with those outcomes. Participants know that others might have some privileged information, but do not know what that information is, and discussion serves as the mechanism through which the parties reveal this information to one another. In revealing correct, fuller or simply better organized information, deliberation act as a vehicle for participants to arrive at more considered judgments themselves and to affect collective decisions through its influence on the judgments of others.

For deliberation to influence individual or collective decision-making, it must bring about a change in how participants' evaluate their options for achieving their goals (Morrow 1999: 86; Landa and Meirowitz 2009: 427f.). Debate creates opportunities for actors to persuade others of the relative value of particular alternatives and so influence their decisions. In the game theoretical literature, such 'persuasion' amounts to changing the beliefs of others about how particular actions yield particular outcomes. What can change in the course of deliberation is thus not how participants evaluate their ultimate goals, but instead their assessment of how best to achieve those goals, given their beliefs about the likely effects of various actions and the expected behavior of others (Austen-Smith 1990: 124f.; 1992: 45). Deliberation is therefore important not

because debating collective decisions compels actors to verbalize and justify their actions and in the process reconsider and revise their interests. It is rather important because it allows actors to exchange private information and thus fashion strategies to help overcome the uncertainties that prevent actors from cooperating with one another (Culpepper 2003: 21). Deliberation allows actors to assume common knowledge and hence facilitate the alignment of expectations: through discussion, participants can improve confidence in the intentions of others, exchange mutual commitments and learn to trust whether or not others will honor them (Ostrom 1990: 138f.; 1998).

The principal dilemma for discussion as a means of coordinating behavior is of course that participants can have strategic incentives to distort their special knowledge or hide their true intentions. Misrepresentation or deception can trick others to take actions that are not in their interest. Some of the thorniest problems in politics arise precisely, when participants are uncertain about the intentions of others and thus whom to trust. Unless information volunteered in the course of discussion can be verified, participants must rightly be suspicious of its accuracy, validity and reliability. Discussion will therefore only be efficacious insofar participants believe that others are telling the truth (Fearon 1998: 47; Austen-Smith 1992: 46). As a consequence, game theoretic models of deliberation are necessarily centered on the circumstances that encourage participants to truthfully reveal private information and induce their interlocutors to accept it as credible. Rather than look to the (ideal) deliberative behavior that will lead to better decisions, this view of deliberation then directs attention towards the institutions within which actors deliberate (Austen-Smith and Feddersen 2006; Landa and Meirowitz 2009: 429f.).

In the varieties of capitalism tradition, a capacity to deliberate presupposes "institutions that encourage the relevant actors to engage in collective discussions and reach agreements with each other." (Hall and Soskice 2001: 11). Actors rely on these institutions to break down barriers to effective communication, eliminate incentives to transmit deceitful information and thus buttress the credibility of their commitments. Deliberative institutions convert single exchanges into repeated discussions in which a reputation for trustworthiness can potentially mitigate short-term opportunism (Mackie 1998: 84f.; Schneider *et al.* 2003: 144). Because participants can reasonably expect to meet again in the future, joint membership of deliberative fora allows participants to cultivate reputations for providing accurate, reliable and valuable information. Ongoing discussion permits actors to periodically check and verify information volunteered by others and assess whether or not they can be trusted. Those, who are caught lying, can be rebuked and are thus reminded of the cost of deception. Systematic misrepresentation can earn participants a reputation for dishonesty and hence risks ostracism from the group or at the very least the

possibility of being ignored in future discussions. As Elinor Ostrom (1990) demonstrates graduated sanctions allow rule-breakers to observe that defections are uncovered and learn how others will respond to them: an incremental process of verification and graduated penalties affords participants opportunities to increase or decrease their trust in the reliability of others, circulate information about reputations, and over time learn how to cooperate with one another.

If successful, discussion can lead actors to change their expectations about the probability that others are telling the truth about their intentions or special knowledge (Ostrom 1990: 138f.; 1998: 13). Deliberative fora can thus facilitate collective discussion about joint problems, and allow participants to develop a common diagnosis of the situation, share information about the consequences of different actions, build mutual expectations and hence improve confidence in the strategies likely to be taken by others (Culpepper 2003: 17; Hall and Thelen 2009: 12f.). By encouraging participants to share information about their interests and beliefs, deliberative institutions can in short enhance the capacity for cooperative behavior and contribute to mutual expectations that others can be trusted to honor their commitments.

In regulatory politics, deliberative institutions preeminently, but not exclusively,[7] take the format of advisory bodies that allow state bureaucrats to consult outside expertise and garner the views of stakeholders. Advisory bodies at the same time provide venues through which officials can communicate their agendas, priorities and preferences to external stakeholders. State agencies usually, albeit to varying degree, funnel their agendas through expert committees, and – depending on the scope of involvement – such deliberative bodies can exercise considerable influence on regulatory decisions, programs and policies. Committee membership allows stakeholder representatives to participate in collective policy deliberation, decision-making and implementation (Ashford 1984: 73; Leifeld and Schneider 2012: 732). Advisory bodies, which put industry experts in permanent and close contact with their academic and governmental peers, can therefore promote candor in communication: ongoing dialogue on the scope and causes of regulatory problems creates opportunities for members to develop a common diagnosis of a given issue, gather, process and exchange information about the consequences of different decisions and craft agreed recommendations.

Regular discussion among officials and industry representatives can thus strengthen mutual expectations that the views and interests of industry will be considered as new issues emerge. Should regulators for instance decide on urgent restrictions in response to evidence of harm,

[7] Other examples might include formal consultation requirements or informal norms insisting that affected parties should be heard.

without pause to consider industry inputs on control techniques or costs, they may find companies reluctant to volunteer needed information as new substances come up for future review. Companies might likewise wish to distort information transmitted in the course of advisory proceedings. Should a deception be uncovered, however, state authorities certainly have ways to make life more difficult for uncooperative regulatees. Ongoing discussion of regulatory priorities and policies allow participants to build trust and develop relations which encourage candid exchanges about potential sources of harm and their possible solutions. Institutionalized policy deliberations of course do not preclude disagreements or conflicts over the scope and direction of chemical control policies (Knight and Johnson 2007: 56). But they do accord regulators and industry representatives regular opportunities to settle their differences through debate and negotiation.

Discussion channeled through standing committees and similar deliberative fora permits participants to improve confidence in the strategies of each other, and they can therefore be essential to address doubts about the credibility of commitments. Participation in advisory bodies afford companies and their representatives opportunities to learn how officials understand the scientific evidence and evaluate the need for and design of new controls. Companies are consequently in a better position to predict how they might react to new information; and how such a reaction might accommodate their interests. Where corporate decision-makers feel confident that officials can be trusted to consider their views and inputs, they may be more forthcoming and honest about sharing sensitive information. Since information is instrumental in shaping regulators' interpretation of the evidence, their diagnosis of and solutions to regulatory problems, this confidence can create compelling incentives for companies to volunteer their expertise and experiences to officials.

Absent secure channels to communicate agency agendas and designs, industry is in contrast placed in a more precarious position. Unstructured engagements do not give industry representatives the same opportunities for 'a meeting of minds', and they are consequently left guessing about possible ulterior motives. Insulated bureaucratic decision-making processes broken only by *ad hoc* consultations tend to obscure the bigger picture. With no permanent venue to organize and promote discussions of regulatory priorities or how evidence of harm should be interpreted, there is little basis for regulators and companies to develop common understandings of joint problems or establish mutual expectations about their possible solutions. Unable to gauge the intentions of state bureaucrats, companies are left without a reliable basis to predict how they might react to new information; and whether and how such a response might consider industry

Table 2.1 Institutions of Chemical Control and Their Expected Effects on Business Behavior

	BUREAUCRATIC AUTONOMY	
Regulatory Powers	State bureaucrats endowed with broad discretionary authority	State bureaucrats enjoy limited discretionary authority
	➢ The limited prospect of political or judicial interference in regulatory proceedings reduces uncertainties about the direction of state policies	➢ The prospect of political or judicial interference in regulatory proceedings creates uncertainty about the direction of state policies
	➢ Corporate strategies to influence state policies target state bureaucrats	➢ Corporate strategies to influence state policies target multiple political actors
	➢ State authorities are able to accommodate industry views and concerns	➢ State authorities are unable to accommodate industry views and concerns
	➢ Absent recourse to the courts, parliaments or other executive actors, companies face compelling incentives to divulge sensitive information as a strategy to influence administrative agendas, priorities and policies	➢ The unpredictability of regulatory responses, coupled with opportunities to influence regulatory outcomes through access to other decision-making venues, creates few incentives for companies to volunteer sensitive information
Bureaucratic Commitments	Credible	Ambiguous
Business Response	Disclosure	Nondisclosure
	DELIBERATIVE INSTITUTIONS	
Nature of Advisory Proceedings	Comprehensive industry participation and representation	Limited industry participation and representation
	➢ State authorities funnel their regulatory agendas through advisory committees and stakeholder fora	➢ State authorities do not maintain an ongoing dialogue with industry on their regulatory agendas
	➢ Through regular discussion, participants develop common understandings of joint problems and mutual expectations about their possible solutions	➢ Regulators and industry representatives do not develop common understandings of joint problems or mutual expectations about their possible solutions
	➢ Companies learn how state bureaucrats might react to new information and how such reactions might accommodate their interests	➢ Companies are unable to predict how state bureaucrats might react to new information – and how such a response might consider their interests
	➢ Confidence in the designs of state bureaucrats creates strong incentives for companies to volunteer sensitive information	➢ Uncertainty about the designs of state bureaucrats and the unpredictability of their responses hampers incentives to volunteer sensitive information
Bureaucratic Commitments	Credible	Ambiguous
Business Response	Disclosure	Nondisclosure

views and interests. Uncertainty about the designs of state bureaucrats and the unpredictability of their responses consequently hampers incentives to volunteer information.

CONCLUSION

In closing this chapter, let me briefly summarize: in areas of high scientific and technical uncertainty, such as nanotechnologies, new information can exercise significant influence on regulatory agendas, priorities and policies. This can work in industry's favor, if disclosing information succeeds in convincing state bureaucrats to make decisions that reduce anticipated costs or increase private benefits. But companies must also be cautious of sharing sensitive information with regulators: once revealed, information cannot be retracted and its release could severely infringe on corporate interests. Companies will therefore only volunteer information to state authorities if they are confident that it will not be used to the detriment of their interests. Whether companies will decide to disclose, bias or conceal information in other words depends on the expected behavior of their regulatory adversaries and the nature of their commitments.

Countries differ in their organization and processes of chemicals control; and companies are thus presented with different kinds and amounts of information about the probable future behavior of state bureaucrats. Two features I submit of national chemical control regimes are responsible for the capacity of state authorities to commit to cooperation with industry: the regulatory powers of state bureaucrats and their reliance on deliberative institutions in the formulation and implementation of chemical safety policy. Table 2.1 outlines the expected effect of bureaucratic autonomy and deliberative institutions on corporate decisions to disclose or withhold information from state bureaucrats as well as the processes translating the institutional effects into the predicted business responses. Where companies in short believe that the decisions of chemicals policy will consider their views and interests, they may readily entrust state bureaucrats with sensitive information about their operations. Where companies in contrast have reasons to doubt the credibility of a commitment to pursue a set of predictable control policies, they must remain vigilant to possible concealed agendas or the prospect of political or judicial interference in regulatory proceedings. Nondisclosure is a rational business response, when companies cannot predict how state bureaucrats intend to use the information they request from industry.

CHAPTER THREE

A Decade of Uncertainty: American and European Nanotech Policies, 2003-2013

Spurred by concerns over the relatively unrestrained market entry of an increasing number of nano-enabled products, awareness of nanotechnologies has risen dramatically among governments, investors, environmental activists, and companies alike. Given the uncertain risks of nanomaterials, the question facing regulators, industries and other stakeholders was thus from the onset not *whether* the state should intervene to guarantee public health and safety, but *how*. This chapter documents how that intervention has unfolded in Britain, the United States, Germany and Denmark over the decade since nanotech first emerged as an issue on the international regulatory agenda in 2003. In what follows, I examine the policies developed to assess and control the risks of nanomaterials and compare the role of industry in the four countries' policy processes. I show how the desire to reap the benefits of nanotechnologies has led decision-makers in America and Europe to adopt very similar policy strategies; and I demonstrate how the reactions of companies differ across the four countries.

To evaluate my argument, we need to know whether and to what extent companies are disclosing information to regulatory authorities. We may gain some initial traction on this question by analyzing public-private research ventures and industry responses to governmental appeals for voluntary data disclosure. Joint safety research and voluntary reporting initiatives raise delicate and complex issues of confidentiality, data access and ownership. By assessing whether and under which conditions companies have agreed to assist in the generation of new knowledge or participate in initiatives intended to facilitate access to existing industry information and experiences, we can establish a first baseline for evaluating the degree of disclosure. Safety research and voluntary reporting schemes constitute linchpins of governmental risk management strategies; yet, cooperation in these areas is not the only or indeed most important source of information for state bureaucrats. Direct communications with industry representatives in the course of consultative proceedings represents a richer source of information. What is being communicated in any given policy discussion is of course rarely readily observable. But we can

nonetheless approximate the degree of disclosure by evaluating patterns of interactions among regulators and industry representatives; in particular, the *frequency* of interactions and their *conduct* will indicate the extent of information communicated to regulators.

First, information exchange is obviously contingent upon the opportunities for giving input as well as the range of issues on which regulators seek advice. Frequent and regular interactions increase occasions for companies to present their views and offer advice. Unstructured engagements and *ad hoc* consultations on a case-by-case basis in contrast limit the opportunities for companies to voice their positions and press their demands on governmental decision-makers. If regulatory officials value the input of social actors by the utility of expertise they bring to the table, we can reasonably assume that the frequency of contacts capture elements of both the extent and quality of information transmitted to state authorities (Majone 1997; Reenock and Gerber 2008: 419). A second clue is provided by the conduct of interactions among regulators and industry representatives. Policy discussions conducted under the guise of formal proceedings, insisting on transparency, increases the number of parties privy to sensitive information and inhibits the ability to protect confidentiality. Procedural transparency in consequence acts as a barrier to candid discussions about potential sources of harm and their possible solutions (West 2004). Less formal interactions, as Cary Coglianese and colleagues note (2004: 319), in contrast promotes information transmission to regulators, just as it facilitates gossip in everyday life. The opaque nature of informal interactions preserves discretion and protects the privacy of communications; and companies may therefore be more forthcoming and honest about sharing sensitive information.

Differences in the extent, format and timing of industry participation in the policy process in short provide us with indications of the degree and nature of information volunteered to regulatory authorities. Accordingly, for each country, the analysis proceeds in two steps: I first consider the role of companies and their representatives in relation to the formulation and implementation of strategy measures, safety research and policy initiatives designed to provide the necessary basis for risk assessment and management of nanomaterials. Based on the observed frequency of interactions and their conduct, I conclude by assessing the degree of information disclosure and the character of relations among state authorities and industry.

REGULATING NANOTECHNOLOGIES IN BRITAIN

In Britain, the regulatory agenda for nanotechnologies was set with the publication of a 2005 Government Action Plan (HM Government 2005); in the wake of its publication, several

initiatives were undertaken, which in a relatively short time span set Britain on a regulatory path of ongoing stakeholder engagement and public dialogue; promotion of nanotechnology research and development; and active participation in international efforts to assist in a more informed response to the potential human health and environmental risks of nanotechnologies. Guiding these activities was an ambition of 'getting it right' by ensuring that Britain "reap[s] the benefits and avoid[s] the pitfalls." (HM Government 2005: 1). In response to the ubiquitous knowledge gaps collaboration with industry was from an early stage embraced as a strategic measure to advance the regulatory agenda. Governmental decision-makers have in turn come to favor a strategy designed to encourage dialogue among regulatory authorities and industry. By granting access for their representatives to key decision-making venues, HM Government in other words swung the door wide open for companies to seek influence over the direction of UK nanotech policy. Industry has not been oblivious to the opportunities inherent in this regulatory strategy; rather, industry representatives have grasped every opportunity to consult and press their views on state authorities. Ongoing dialogue among officials and corporate representatives has in turn provided the impetus for comprehensive government-industry cooperation intended to advance the regulatory agenda. British companies for their part have sought to cultivate close and collaborative relationships with regulatory officials, resulting in extensive policy discussions, accommodation and broad agreement on the course of British nanotechnology policy.

Risk Management Strategies and Safety Research Policy

Public support for nanosciences and technologies began in the late-1980s. Yet, the story of nanotech regulation in Britain only kicks off with the April 2003 publication of Prince Charles' sharply expressed views on nanotech, including the fear of a future 'grey goo' scenario.[1] A similar intervention by Charles in 1999 had precipitated and reinforced much of the subsequent hostility to GMOs in the British public; and concern that this new intervention and the resounding debate in its wake should likewise taint public confidence in nanotechnologies, prompted HM Government to respond urgently. In June 2003, the Royal Society and the Royal Academy of Engineering were commissioned to investigate the potential environmental, health and safety implications of nanotechnologies. The two Societies published their report, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*, in July 2004. While rejecting calls for a moratorium

[1] 'Grey goo' describes a doomsday scenario in which nanoscale robots self-replicate out of control, producing unlimited copies of themselves, consuming all available material and ultimately laying waste to the planet (RS and RAEng 2004: 109).

on development, the report concluded that the virtual absence of data pertaining to nanomaterials represented clear challenges to effective risk management, and the two Societies in consequence urged a precautionary stance, combined with various recommendations intended to bridge existing knowledge gaps (RS and RAEng 2004:xii). Widely credited with having invigorated the regulatory debate in Britain and abroad, the report created the impetus for a spur of governmental initiatives to "ensure that the public and those who work with nanotechnologies feel confident that Government actions being taken are appropriate, proportionate and effective […]." (BIS 2010: 35). Welcoming the two Societies' conclusions and recommendations, HM Government responded with an initial action plan in February 2005.

Under the 2005 action plan, HM Government launched an immediate and multifaceted research program directed at addressing current uncertainties about the ecological behavior and toxicological properties of nanomaterials. An inter-ministerial Nanotechnology Research Coordination Group (NRCG), chaired by the Department for Environment, Food and Rural Affairs (Defra), was established to monitor progress and coordinate UK research initiatives. Under the auspice of the NRCG, 19 research objectives have been named and taken forward by five task forces. With the NRCG acting as steering body, the UK research program constitutes a cross-government effort, which draws upon expertise from governmental departments and agencies, the UK Research Councils, academia and industry. As part of its remit, the NRCG links to international partners, particularly the OECD and the International Standards Organization, with an aim to encourage knowledge exchange, avoid unnecessary duplication of research, and ensure the development of common standards for nanotechnology (Defra 2005; 2006a; 2007). HM Government's research policy has thus served two, often complementary, objectives. With a priority to increase the understanding of manufactured nanomaterials and their potential risks, the NRCG has on the one hand supported the collection of scientific evidence and experience required to guide future decisions on appropriate control mechanisms. On the other hand, to ensure that knowledge and ideas generated by fundamental research can be transferred to industry for commercial applications, governmental agencies have focused on establishing mechanisms to support collaborative research between industry, academia and other relevant bodies (Defra 2007).

The UK research program draws on the capabilities of domestic research institutions and international networks. From the program's initiation, however, the persistent information deficiencies regarding use patterns, exposure pathways and endpoints created significant obstacles for attempts to prioritize research intended to underpin risk assessments and the development of regulatory controls. As one Defra official explained, this not only created a problem of directing

research efforts; it also urgently accentuated the need to gauge the level of immediate risks to human health and the environment.[2] HM Government in consequence recognized the need for regulatory authorities "to develop links with industry to deliver the necessary research on the basis of need in the context of specific products and applications of nanotechnologies."(HM Government 2005: 9). In an effort to promote knowledge exchange, representatives from industry were therefore encouraged to join the five NRCG task forces. Deliberations among governmental scientist, academic researchers and industry experts in the various task forces have in turn served to identify areas of concern, facilitate agreement on the major challenges facing reliable hazard identification, and ultimately inform research priorities (Defra 2007). In the words of a Defra official: "I think nanotechnology broadly is an area where we can be quite proud of our ability to collaborate with industry and with academia and the [NRCG] is a good example of that."[3]

As in other countries, ensuring a coordinated response to enable targeted safety research and avoid unnecessary duplication has been a key priority in the United Kingdom. For this purpose, a Ministerial Group on Nanotechnology was convened in 2007 to monitor and coordinate funding decisions, research initiatives and regulatory policies (HM Government 2008). Reporting directly to this overarching ministerial group, the NRCG – and similar inter-ministerial groups convened since 2005 – has thus provided a platform for consultation and information exchange among government officials as well as among officials and stakeholder experts. Despite recommendations by the Council for Science and Technology (2007) to assign overall funding responsibility to a single governmental body, the power to allocate funds and instigate actions has however remained with individual departments and agencies. Governmental entities have committed significant resources to enable safety assessment of nanomaterials – often implemented through initiatives discussed and agreed with industry. Both the Health and Safety Executive (HSE) and Defra have for example maintained ongoing dialogues with UK manufacturers and users of nanomaterials; and both have initiated and sponsored a range of joint industry projects and surveys.

HSE initially drew together industrial stakeholders at a major international symposium on occupational health aspects of nanomaterials organized in October 2004 (HSL 2004); and discussions with corporate representative and industry experts have since continued under the agency's network of advisory committees, boards and industry councils. HSE mission-oriented

2 Interview, London, March 3, 2011.
3 Interview, London, March 3, 2011.

research program has strongly encouraged collaboration with industry to facilitate an understanding of industry sectors, risks and exposures in support of the development of good practice guidance (HSE 2009a). Like other UK authorities, HSE participates in and co-funds joint public-private research consortia, such as *e.g.* the international NOSH Consortium,[4] with an aim to leverage expenditures and facilitate access to research data and experiences.

Defra has likewise contracted extensively with the private sector under the ministry's program of intra- and extramural research, with industry representatives serving on various project steering groups. The Nanotechnology Industries Association (NIA) – a trade body representing the interests of UK nanobusinesses – alone has been awarded several commissions focused on gathering evidence to support reliable exposure assessments. In addition to its role as private contractor, the association acted as interlocutor between government and industry, processing and aggregating responses to governmental information requests as well as facilitating contacts between regulators and individual companies. Encouraging joint public-private partnerships thus constitute a cornerstone of HM Government's risk management strategy – an approach best exemplified by Britain's contribution to the global safety assessment of nanomaterials under the OECD *Sponsorship Program*.

Launched as a 50:50 public-private-partnership in 2009, the PROSPEcT[5] project brought together agencies and public research institutions, several university laboratories and industry as joint sponsors. Each partner was represented by a senior researcher, who oversaw the consortium's contributions and progress. Funded with £3.7 million, PROSPEcT represents one of the largest single contributions to the OECD Sponsorship Program. The consortium sought to produce new data concerning material characterization for two agreed nanomaterials (cerium oxide and zinc oxide) as well as develop seminal eco-toxicological test methods and protocols. PROSPEcT was expected to deliver important insights on the properties of these materials as well as improve the general reliability and feasibility of traditional toxicological methods. At the same time, PROSPEcT was also intended to promote the ability of UK companies to compete internationally by acting as a bridge to bring research on these nanomaterials to market. With the NIA acting as consortium manager, and the in-kind financial, scientific and technical contributions of its members, PROSPEcT thus nicely illustrates how cooperation, according to

4 The Nanoparticle Occupational Safety and Health Consortium was formed in December 2005 as a public-private-partnership intended to develop instrumentation needed to detect airborne nanoparticles and related test methodologies (See HSE 2007; Ostraat 2010).

5 Ecotoxicology Test Protocols for Representative Nanomaterials in Support of the OECD Sponsorship Programme.

one official, has allowed HM Government to share the burden of a 'massive' research agenda with industry.[6] For corporate participants, joint safety research entailed several benefits, including not only direct financial savings on toxicity testing, but also a visible commitment to the safety of their products. A more subtle benefit, if potentially of greater strategic value, was the opportunity to influence the basis for future regulatory decisions by shaping the design and methodology of QSARs[7] used for predictive safety evaluations of novel nanomaterials.

From a corporate risk-benefit perspective, however, joint research is not unproblematic: negative toxicity findings can generate adverse publicity and could fuel new regulatory restrictions. Given the high stakes riding on company test data, the design of research partnerships has nonetheless sparked remarkably little friction and has not dissuaded UK companies from contributing to joint safety ventures. Neither has the policy of sharing data from industry-sponsored research through the NRCG or other coordination bodies been perceived as a significant impediment to cooperation. In working jointly with governmental scientists and independent researchers from academia, UK companies have in short been forthcoming in setting aside what often prove controversial issues regarding study design, test protocols and reporting (McGarity and Wagner 2008; Monica and Monica 2009) – with HM Government in return accommodating corporate concerns over data ownership and access.[8] The impact on research priorities, and hence ultimately on regulatory decision-making, leveraged by this information instead hints at the strong incentives for British companies to volunteer information to regulators.

Voluntary Reporting Initiatives

Beyond support for safety research, a second strand of HM Government's regulatory strategy has been directed at gaining access to existing data and experience from industry. In September 2006, following extensive consultations with stakeholders, Defra introduced a two year trial Voluntary Reporting Scheme (VRS) for engineered nanoscale materials. Defra specifically sought information on the types and volumes of nanomaterials being manufactured, applied, and marketed as well as information on current risk management practices. Information submitted under the VRS was intended to assist Defra in determining levels of exposure and identifying possible risks to human health and the environment. Additionally, the scheme was meant to

6 Interview, London, March 3, 2011.
7 Quantitative Structure Activity Relationships.
8 Interview, London, March 3, 2011.

gather information need to evaluate existing regulatory mechanisms, while enabling a more informed debate and ultimately decisions about the nature of appropriate controls (Defra 2006d; 2008a; 2008b).

As the name suggest, the VRS was entirely voluntary and did not replace any existing reporting requirements. Defra did – briefly – consider the possibility of introducing new statutory requirements for nanomaterials, but ultimately abandoned the idea: a mandatory reporting requirement would have required new primary legislation, which was never on HM Government's agenda. One Defra official laconically explained "even in those days it was quite a politically difficult thing to do."[9] Weighing on this decision was also concerns that mandatory reporting would "erode good will from industry […]." (Defra 2006b: 50) A further complication arose from the absence of clear definitions: a mandatory scheme would have run into problems of distinguishing between producers and non-producers of nanomaterials, making enforcement not only administratively difficult, but also burdensome to industry. A mandatory reporting requirement was on several counts then considered politically unattractive and technically infeasible. A voluntary scheme was in contrast viewed as the best low cost instrument to quickly shore up the evidence base. An added benefit was that a voluntary approach might build "trust with industry and other stakeholders, and [provide] them with an opportunity to be involved in policy development at an early stage." (Defra 2006b: 49)

As with similar initiatives in other countries, participation in the VRS has been limited: only 13 submissions were received at the end of the two year period. Defra never appear to have set a clear baseline for how many submissions to expect. While the outcome has been described as disappointing, Defra has officially taken the position that the low number of submissions reflects 'the state of industry'. Whether a 'grave disappointment' or reflecting 'commercial reality', Defra had been warned that the large amounts of information requested, the resources needed to participate (especially with respect to SMEs) and particularly concerns regarding confidentiality might create significant obstacles to participation (Defra 2006c). Aware of such potential barriers, Defra made several concessions to accommodate the views and interests of industrial stakeholders.

Initial consultation drafts for example made few specific allowances for the protection of intellectual property rights (Defra 2006b). Fearful of the implications for their competitiveness, industry representatives mounted pressure for Defra to issue a clear statement about the status of

[9] Interview, London, March 3, 2011.

submitted data, including ownership and how reported information would be used by the ministry. Defra in turn guaranteed that any data submissions would be treated as confidential unless "expressly given permission by the data owner to do otherwise [and] consult the person who provided information should that information be subject to a request under the provisions of the Freedom of Information Act." (Defra 2006d: 6) Defra moreover clarified that data would be held by the ministry, but "would be shared across Government as necessary for the development of appropriate controls." (Defra 2006b: 24) The NRCG was asked to monitor and manage the use of reported information across government agencies; an arrangement welcomed by industry with the caveat that industry representation should be ensured during NRCG discussions of the data – a recommendation ultimately borne out as membership of the five taskforces was supplemented with industry experts.

Finally, to facilitate industry participation, Defra engaged the NIA as intermediary: with industry skeptical of the value of the VRS, the NIA in turn assumed an instrumental role in the design and fate of the VRS. In fact, of the 13 submissions to the VRS, all industry submissions were made by NIA members, many anonymously through the association as an agent. In several instances, NIA staff sought out SMEs to assist them with completing the reporting form. The upshot of this direct involvement is that the association was in a position to, if not control, then at least keep abreast of the flow of information to regulators, ultimately reducing the risk that members experience unwelcome 'surprises'. The value of the NIA as a trusted interlocutor can best be illustrated with Defra's unsuccessful attempts to garner additional submissions. When Defra, disappointed with the initial nine responses in early 2007, commissioned the Nanotechnology Knowledge Transfer Network to solicit participation from another 1.100 companies, it succeeded in securing only *one* additional submission.

13 submissions may not seem of much; however, although quantitatively not impressive, the information received under the VRS did as an official explained enable government to

> "take a view on the quality of data that was being provided, on the quality of research that industry was doing, looking into the risks and benefits of particular nanomaterials. It enabled government to satisfy ourselves that particular nanomaterials were pretty much as safe as they could reasonably be expected to be. We were able to satisfy ourselves that there was no need to remove things from the market."[10]

Given the pervasive information deficiencies regarding use and exposure patterns, gaining access to detailed and specific product information, data and industry experiences did assist attempts to identify and mitigate potential risks; and in a broader sense, the VRS served as an important

[10] Interview, London, March 3, 2011.

enabler of HM Government's ambition of managing the potential human health and environmental risks of nanotechnologies. In return for its role as interlocutor between government and industry, the NIA – much to the frustration of some within the NGO community – managed to secure significant concessions on the overall design of the VRS, particularly in relation to issues of confidentiality.[11]

Regulatory Relationships in Britain

The policy process in Britain has above all taken shape by a commitment to collaboration with industry, civil society groups and the research community. In support of this commitment, governmental decision-makers has encouraged close and regular contacts among regulatory officials and industry representatives as the basis for an ongoing dialogue about research directions and the nature of appropriate controls. Corporate representatives and industry experts have been invited to participate across a range of decision-making venues, with governmental departments and agencies actively seeking the advice and views of industry on all major policy initiatives. Asked about the motivation for this strategy, one official bluntly exclaimed: "We have to, we have no choice really! The research agenda is massive and we can't go it alone. We have to work together […] Hand in hand we move forward in a far better way than we can divided [and] industry is playing its part rather much."[12]

Indeed: UK companies have not hesitated in their response to the opportunities entailed by the invitation for dialogue and cooperation. Through informal consultation, negotiation and collaborations, industry has left a distinct mark on the development of UK nanotech policies, and has significantly contributed to building the scientific basis available to regulators for risk assessments of nanomaterials. UK safety research policies and regulators' requests for existing industry information are thus characterized by dense and informal discussions among governmental entities, UK companies and their representatives. Despite arguably meager interest in the VRS, the initiative nonetheless demonstrates how disagreements have been approached in a spirit of accommodation, rather than confrontation. British companies have sought to cultivated close and congenial relationships with regulatory officials, resulting in extensive deliberations, compromise and broad agreement on the direction of British nanotechnology policy. Cooperation on advancing the regulatory agenda is thus in short an essential feature of the policy process in Britain. By joining with industry, HM Government gained access to information

11 Interview, London, March 3, 2011.
12 Interview, London, March 3, 2011.

not only crucial to gauge the need for immediate action, but also to adopt a clear set of strategic priorities. Industry has obviously not volunteered this information out of 'corporate altruism'; rather, UK companies have in HM Government's invitation to join in the policy process seen an opportunity to shape regulatory policies to their strategic advantage. To better appreciate the implications of this response, and the degree and nature of information volunteered to regulatory authorities, we will next consider the contrasting experience of nanotech regulation in the United States.

REGULATING NANOTECHNOLOGIES IN THE UNITED STATES

Under the National Nanotechnology Initiative (NNI), a presidential initiative announced in 2000, the Federal Government has adopted and promoted much the same range of policy instruments and research initiatives as HM Government: like Britain, the United States has committed significant resources to address uncertainties about the ecological behavior and toxicological properties of nanomaterials; like Britain, federal agencies have sought to canvass the views of stakeholders to inform the development of regulatory policies; and like Britain, the United States has prioritized active participation in international efforts to assist in a more informed response to nanotechnologies. Finally, like HM Government, federal decision-makers have strongly emphasized the strategic value of partnerships with industry and other stakeholder groups. At face value, then, the Federal Government would appear to share British perceptions of the challenges created by nanotechnologies – and their possible solutions. In contrast to Britain, however, comprehensive cooperation among government and industry never materialized. While presented with ostensibly similar prospects of shaping regulatory outcomes, American companies have been reluctant to embrace the strategies of their UK competitors. Rather U.S. companies have displayed manifest discomfort in cooperating with the federal regulators, resulting instead in patterns of formal and unstructured engagements.

Risk Management Strategies and Safety Research Policy

The National Nanotechnology Initiative, enacted by Congress in November 2000 and formally established in fiscal year 2001 with an initial investment of US$ 422 million, was created to provide a formal mechanism of coordination across federal nanotech research and development initiatives (NSTC 2000). The NNI aims to coordinate the activities of its 25 constituent agencies, provide funding for university laboratories, and support for U.S. companies pursuing commercial applications of nanotechnologies. NNI agencies participate in a variety of international fora to

cooperatively address issues related to metrology and standards, nomenclature, and nanoscale materials characterization. In 2003, Congress provided statutory foundations for the activities of the NNI through the *21st Century Nanotechnology Research and Development Act*. As mandated by the act, the NNI has developed, and periodically updated, a number of strategic plans (NSTC 2004; 2007; 2011b) that provide the framework within which each agency carries out its own mission-related nanotechnology programs. With the 2004 strategic plan, four overarching goals were identified – three focused on accelerating commercial applications, and a fourth intended to ensure the safe and responsible development of nanotechnologies by supporting "a broad spectrum of research to evaluate environmental, health and safety impacts […]." (NSTC 2004: 10)

In support of this goal, a Nanotechnology Environmental and Health Implications (NEHI) working group was created in 2003. Deliberations within the NEHI group are intended to facilitate inter-agency information exchange related to their human health and environmental activities. Informed by discussions among NEHI members, the NNI has adopted a number of strategies specifically targeted at environmental, health and safety research (NSTC 2006; 2008; 2011a). A recurring theme of the NEHI strategies is the need to leverage research funded by other governments and the private sector. The 2006 *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials* document, for example, emphasized that "it is clear that not only is coordination of research activities among the NNI agencies important, but also collaboration with industry and with other governments will be necessary in order to expedite progress." (NSTC 2006:vi)

Promoting partnerships with corporate stakeholders, while improving coordination among government, academia and industry, has thus emerged as a clear priority of federal nanotech policy. Most observers agree however that this has largely proven a wishful, if not naive, ambition – one, which the NNI has failed to realize. A NNI official acknowledged: "we are trying to do a better job of partnering with [industry] to get them to fund research. […] You will see very sector specific partnering […] but comprehensive [collaboration] or partnering for fundamental research – that's harder!"[13] An EPA official put it more candidly: "This criticism that the NNI is going to coordinate research [with industry], I don't see that happening, because what Dow Chemical wants to research is going to be very different from federal agencies. The best you can probably

[13] Interview, Washington, D.C., April 23, 2012.

do is get people to at least share more information."[14] Industry insiders have in the same vain tended to reject the idea of coordination.[15]

This lack of interest can in part be explained with the neglect of measures to support collaboration. While the NEHI group for example operates with much the same mandate as the NRCG, deliberations are conducted in what critics describe as a 'federal vacuum' (National Research Council 2009: 48), devoid of direct input from companies or other stakeholders. NEHI is representative of the general situation. NNI has yet to establish a permanent channel through which stakeholder views can flow into the development and execution of research priorities and initiatives. The NNI instead rely on a more *ad hoc* format with inputs from stakeholders primarily secured through open workshops and formal consultations. Absent regular and direct access to NNI officials, U.S. companies have enjoyed fewer opportunities to shape decisions on research strategies and spending during their formative stages than their British competitors. But why have U.S. companies not mobilized to push for access to coordination bodies like the NEHI?

The answer must, partly, be sought with the structure of the NNI: first, under the Nanotechnology Act, the NNI has interpreted its mandate as primarily promoting innovation and advancing commercial applications of nanotechnology. Although the act calls for NNI to ensure that human health and environmental concerns are integrated within broader federal nanotechnology research and development activities, skeptics question the initiative's commitment to safety research; for example "they give lip-service to environmental health and safety issues, but that is not their primary focus. If you look at the law, the last thing on their list is safety and environmental health. […] Their attitude at times seems to be: 'there have been no problems yet, so why do we need to worry about this'."[16] Secondly, congressional funding for the NNI is provided through appropriations to each of the 25 participating agencies. The NNI itself has no centralized source of funding. The NNI, including NEHI, therefore has essentially no leverage over individual agencies (National Research Council 2009: 50). As an EPA official explained, the NEHI group

> "is a good place to exchange information – to find out what the other agencies are doing. But what people don't realize about the NNI is that they have no direct authority over each agency's funding. While EPA might have 10 million dollars [to fund research], *EPA* decides what to do with that. They can have some influence through this inter-agency group, but no decision-making."[17]

14 Interview, Washington, D.C., April 19, 2012.
15 Interview, Washington, D.C., April 16, 2012.
16 Interview, Washington, D.C., April 19, 2012.
17 Interview, Washington, D.C., April 19, 2012.

If not a NNI priority, and with risk-related decisions made elsewhere – at the agency-level – it is hardly surprising that U.S. companies have displayed little interest in securing access for their views and regulatory interests.

Unlike the 'top-down' coordination approach embodied in the NRCG, 'bottom-up' coordination in the U.S. has created fewer incentives for industry to engage the NEHI with an aim to shape the direction of federal research priorities and strategies. Yet, looking closer at the executive agencies, we observe much the same pattern of disengagement between officials and industry. Consider U.S. EPA. In 2004, EPA's Science Policy Council formed a cross-agency working group to identify issues related to nanotechnology and the environment. In February 2007, the group released a *Nanotechnology White Paper* (EPA 2007), which presented a number of recommendations with respect to future research needs and regulatory oversight. These recommendations were supplemented with a *Nanomaterial Research Strategy* released in 2009 (EPA 2009a) and since implemented through the agency's in-house research program and the Science to Achieve Results grant program (Savage, Thomas and Duncan 2007).

Like the NNI, EPA has committed to promoting partnerships and dialogue with industry to inform research priorities and policy initiatives (EPA 2007: 63). Nonetheless, the degree of industry inputs to or involvement in agency decision-making processes have to date been marginal. While the agency has conducted various administrative hearings on its risk management policies, EPA has established neither the basis for an ongoing dialogue with industry nor managed to encourage joint research collaborations: companies can for example contribute to the agency's research programs, but they are not eligible to receive grants, and participation is limited to supporting roles. Little wonder then if companies looking to commercialize the results of their research investments have shown little interest in partnering under these terms. Although EPA moreover has solicited public comment through administrative hearings and formal consultations of agency policies and strategies, stakeholder views have not been considered during their formative stages. Research initiatives and policy measures have instead been devised through internal agency deliberations.

EPA's approach is not unique; other agencies with a research mandate for nanotechnology, like the FDA or OSHA, have similarly maintained arm's length relations with industry. While expressing interests in cooperation, the executive agencies have in effect failed to engage industry in a collaborative dialogue. In contrast to Britain, then, U.S. risk management strategies and research initiatives have been formulated and implemented in an environment largely void of government-industry collaboration. There is one notable exception to this general pattern, though. In 2011, U.S. agencies, with Environment Canada, in cooperation with several U.S.

manufacturers announced the launch of a joint research consortium. Managed by the International Life Science Institute (ILSI),[18] the NanoRelease project is intended to identify available methods for evaluating release scenarios during the life cycle of product uses; assess the utility and reliability of these methods as applied to nanoscale materials; identify gaps, where new methods are needed; and eventually to fill those gaps by testing and evaluating selected methods.

The NanoRelease steering committee is composed of risk management experts from government, industry, nongovernmental organizations, and international organizations. Key benefits of the project is expected to include the ability to evaluate and compare nanomaterial releases from commercially available products as well as expedite the development of new products by establishing broadly accepted evaluation methods. Such methods are expected to facilitate the appropriate calibration of risk management measures in occupational, consumer, and environmental contexts (Rizzuto 2012). Unlike the PROSPEcT project, which was intended to provide a full characterization of the analyzed materials, NanoRelease however considers only questions of exposure to nanomaterials. After an initial nine month assessment period, the steering committee selected multi-walled carbon nanotubes as the first nanomaterial to undergo testing, and ILSI is currently recruiting experts for the next phases of the project. NanoRelease thus represents a successful instance of government-industry collaboration; but the joint project remains the exception from the norm of formalized and arm's length interactions among regulators and companies.

Voluntary Reporting Initiatives

In support of U.S. safety research policies, federal agencies have undertaken a range of evidence gathering initiatives to access existing data and practices from industry – with mixed results as illustrated by the experiences of two lead federal agencies: NIOSH and EPA. Whereas the NIOSH program of voluntary site inspections has won wide acclaim as a successful example of government-industry cooperation, evaluations of EPA's Nanoscale Material Stewardship Program range from disappointment to a dismal failure. These voluntary initiatives nicely illustrate the conditions under which federal agencies have successfully engaged industry – and importantly the inherent limitations to cooperation in the United States. Consider each in turn.

The National Institute for Occupational Safety and Health (NIOSH) is tasked with identifying potential occupational hazards from exposures to chemical substances and to provide recommendations for preventing injury and illness. As part of its nanotechnology research

[18] ILSI is a private research institute funded by major U.S. corporations in the food and chemical industries.

agenda, NIOSH created a field team in 2005 to assess workplace processes, materials and control technologies through partnerships with industrial producers and users. To date, the field team has conducted voluntary inspections in a variety of facilities involved in the research, manufacture or use of nanomaterials. The program is fully funded by NIOSH and there are no monetary costs to participants. NIOSH has, moreover, issued extensive guarantees to participating companies that any proprietary information will be protected. The program has allowed NIOSH to gather baseline data to assess potential occupational safety and health implications of engineered nanomaterials. Information which the agency in turn has used to supplement its best practice guidance documents (NIOSH 2005; 2009).

NIOSH is a *research* agency. As such, the agency has no authority to mandate site inspections. But unlike other federal entities, NIOSH has succeeded in securing access to industry information. And U.S. companies have indeed been welcoming of NIOSH's activities. One industry representative exclaimed:

> "NIOSH is really on the leading edge. They have done some really wonderful work on occupational exposures […] They are basically providing a free consultant service to [companies] who didn't have to pay anybody to come in and evaluate their situation or offer any potential solutions. It was a free consultation on NIOSH's part, so both industry benefitted and NIOSH got the data on what was going on, so they benefitted as well."[19]

The representative however went on to emphasize: "NIOSH has the luxury of not being a regulatory agency, so industry is far more welcoming of NIOSH coming into their facility to take a look around, because they are not regulatory."[20] Corporate interest in the NIOSH voluntary initiative thus not only springs from the incentives created for participation; rather, cooperation has been facilitated by the absence of regulatory liabilities. Where such liabilities exist – *i.e.* where *regulatory* agencies have sought to encourage cooperation – the stakes for companies look radically different as illustrated by EPA's unsuccessful bid to convince industry to volunteer information.

Originally intended to run in tandem with the UK VRS, EPA's voluntary reporting scheme, the Nanoscale Material Stewardship Program (NMSP), was delayed until January 2008. The NMSP was developed to provide EPA with a firmer scientific foundation for its nanotech policies by encouraging submission and development of new information for nanoscale materials (EPA 2009b: 3). Like the VRS, then, the NMSP was viewed as an instrument to quickly shore up the evidence base, allowing EPA to avoid a cumbersome rule-making process. That it took EPA three years to finalize the program thus serves as a first indication of the reluctance encountered

[19] Phone interview, May 31, 2012.
[20] Phone interview, May 31, 2012.

by the agency. Unlike the VRS, information submitted under the NMSP was *not* meant to facilitate decisions about future regulatory controls. As one observer noted: "industry would [not] have gone for *that*. It was meant to inform industry about how to be better players until there were regulations, so that when there were regulations they would already be complying."[21]

Notwithstanding the more modest ambition, interest in the NMSP has as in Britain been limited: as of December 8, 2008, a total of 29 companies had submitted information and a further seven companies had outstanding commitments. While the agency's interim evaluation released in 2009 praised the NMSP's achievements (EPA 2009b), EPA officials have in private expressed disappointment – a sentiment widely shared among stakeholders. Unlike Defra, EPA did establish a baseline for success: 240 submissions from about 180 companies. Participation has thus fallen far below the mark, above all with respect to SMEs. While NMSP did yield information on properties, commercial uses and basic manufacturing processes, few submissions provided either toxicity or fate studies (EPA 2009b: 9). Defra as we saw has referred the limited participation to the 'state of industry'. EPA in contrast concluded that the "low rate of engagement […] suggests that most companies are not inclined to voluntarily test their nanoscale materials." (EPA 2009b: 27) In April 2010, EPA announced that data received under the NMSP was insufficiently robust for the agency to make any general conclusions about the risks of nanoscale materials. And that the agency in consequence would begin to consider how its authority under existing federal statutes could be used to promulgate testing and reporting rules for nanomaterials.

Regulators in Britain and the United States thus differ in the lessons drawn from the limited interest in voluntary data disclosure. Defra saw the VRS as an opportunity to maintain a constructive dialogue with industry and other stakeholders (Defra 2006b). The ministry consequently sought to encourage participation through informal guarantees, combined with a policy of proactive accommodation of industrial views and concerns. While EPA likewise undertook an extensive outreach campaign in support of the NMSP, decisions about program structure were ultimately taken behind closed agency doors – a policy heavily criticized by stakeholders. Despite concerns of an industry bias in the agency's nanotech policy (see *e.g.* Rudd 2008), EPA has in fact not been exceedingly accommodating of industry demands. During initial discussions of a voluntary program, industry representatives for example pushed for inclusion of 'safe harbor' provisions (NPPTAC 2005b). Companies, as a participant recalled, essentially

[21] Interview, Washington, D.C., April 17, 2012.

wanted to have no liability as a condition for participating.[22] An agency official observed: "publicly we didn't [reject the idea], but privately [we said:] 'there is no way! If we get the information and there is something we have to act on, we'll act on it. We can't give you that guarantee."[23]

Contrast this with the VRS, where Defra never excluded that submissions could prompt regulatory action. Reported information was moreover fed into ministerial decision-making bodies, where it could – in principle – have propelled a new stricter policy on nanomaterials. And the ministry did this with industry blessing. EPA for its part was unable to share most of the information received under the NMSP with other federal agencies. Under the provisions safeguarding confidential business information in the United States, exchanging information claimed as such across the Federal Government is a notoriously complex affair (GAO 2005; Wagner 2004: 1699ff.). Participants have not surprisingly taken full advantage of these provisions, even to the extent that some companies claimed their identity as confidential (EPA 2009b). While the NRCG do operate within a framework of confidentiality, those familiar with the incentives created by the rules governing confidential business information in the United States would probably find it difficult to imagine companies signing on to a similar arrangement. An official remarked:

> "This is Washington – reality is what you see, and if you don't see it – it's not there. But I know [the information] is there! […] Part of their reluctance to share all that information [arise because they would] have to let out some of the information about what [they] are working on – don't wanna do it! They don't see it in their interest! […] If you let out the information [to demonstrate that products are safe] that would also let people know exactly which chemicals you are making. They are pretty secretive about – especially – specialty chemicals."[24]

Regulatory Relationships in the United States

Like their colleagues in Whitehall, decision-makers in Washington have professed keen interest in partnering with industry groups and other stakeholders. The Federal Government has moreover adopted much the same range of policy instruments as HM Government and has launched on a broadly similar path to enable a coordinated response to nanotechnologies. In contrast to Britain, however, little progress has been made on securing input from and cooperation with industry. This outcome partly reflects the choices of officials: federal entities have been reluctant to draw

22 Interview, Washington, D.C., April 17, 2012.
23 Interview, Washington, D.C., April 19, 2012.
24 Interview, Washington, D.C., April 19, 2012.

in external views during the formative stages of decision-making. Contrast for example the UK policy of letting informal discussions with industry representatives inform research priorities, with the following assessment by a U.S. official:

> "It is inherently governmental for the agencies to decide what research should be funded next […] We are very confidential about the information: what the topic is going to be and what the details are and the science you can propose, until it goes public and everybody sees it together at the same time. The decisions about what to fund and those kinds of things are inherently governmental and only government people can decide them. There are some reasons for having some distance."[25]

Representatives of organized interests have consequently been kept at arm's length. Laments chair of the ACC Nanotechnology Panel, Paul D. Ziegler (2007: 4): "To date, industry's role has been largely restricted to passive review of decisions already made. Industry's considerable experience could be better utilized by being actively engaged earlier in the process […]."

U.S. companies for their part have however been equally skeptical of working closely with regulators. On occasion, partnerships and joint-ventures among federal agencies, research institutions and companies have played a supportive role. Yet, these collaborations fall short of the benchmark set in Britain, and remain exceptions from a more general pattern of unstructured dialogue, isolated engagements and formalized interactions among regulators and companies. The degree of industry inputs to or involvement in federal decision-making and research activities have thus been marginal. Skepticism regarding the intentions and agendas of federal agencies has in turn strongly spoken against a course of volunteering information to regulators. Consider the NMSP: as one industry insider explained,

> "there was a lack of clarity when you signed on to the Nanoscale Material Stewardship Program what exactly you were signing on to. Industry wanted a commitment from EPA that if we say yes we will have to do A, B, C, D and E, but not A, B, C, D, and E *ad infinitum* item. That lack of clarity was a real turn off to a business community that didn't want to open its checkbook to an unlimited amount of data production."[26]

Contrast this with the VRS, where Defra issued nothing but an informal guarantee that the rights of data owners would be respected. While neither scheme can be consider particularly successful, they forcibly contrast the nature of regulatory relationships in Britain and the United States: whereas informal dialogue with manufacturers ensured industry backing for the goals of the VRS, no such support was forthcoming for the NMSP. In fact, a coalition of trade associations only came out in favor of the program, urging companies to submit data, six months into the program (SOCMA, ACC and NanoBusiness Alliance 2008). Curiously, this endorsement

[25] Interview, Washington, D.C. April 23, 2012.
[26] Interview, Washington, D.C., April 16, 2012.

coincided with EPA's announcement a week later in July 2008 that the agency was prepared to issue a mandatory reporting rule, if participation did not pick up – which it did with a sudden 300 percent increase in submissions. Negative incentives more than anything thus appear to explain U.S. companies' receptiveness to EPA's appeals for 'voluntary' disclosure. Following a meeting with EPA officials, industry association SOCMA for example warned members that EPA

> "is eyeing a test rule. […] The test process would be mandatory, and proscribe specific actions for each company. However, SOCMA believes that the issuance of a test rule is not *fait accompli*. If one – or several – companies step forth and express a willingness to complete the in-depth portion of the Nanomaterials Stewardship Program, then the test rule may be held back."[27]

The policy process in the United States is in short characterized by a clear pattern of disengagement, reluctance, formal communications and *ad hoc* encounters among federal entities and industry representatives. Despite generous opportunities to participate in regulatory proceedings through administrative hearings or open workshops, industry has been reluctant to embrace the strategies of their UK competitors. Federal safety research has in consequence remained largely detached from parallel efforts in industry, with regulatory decisions and risk management activities shaped by internal agency processes, insulated from external inputs. One NNI official summarized the sentiment governing nanotech policy in the United States thus: "We'd all like to be friends, but we are a little bit wary of each other based on past experience."[28]

REGULATING NANOTECHNOLOGIES IN GERMANY

German nanotechnology policy is characterized by a commitment to greatly expand the knowledge base on potential risks. Beyond considerable increases in public funding for safety research, a core element of federal nanotech policy has consisted of encouraging dialogues and cooperation with industry. Discussion of potential human health and environmental risks began in earnest in 2005, when the Federal Ministry of the Environment, Nature Conservation and Nuclear Safety (BMU) organized a major international conference on synthetic nanoparticles (Anton *et al.* 2005). Based on recommendations emerging from the conference, the BMU decided to continue an open stakeholder dialogue. In late 2006, the BMU convened the German NanoKommission to foster dialogue and knowledge exchange among government, industry and other stakeholder groups. The German Federal Government would in short appear to have

[27] www.socma.com/pressRoom/?subSec=3&sub=71&articleID=1190 [Accessed April 12, 2013]
[28] Interview, Washington, D.C. April 23, 2012.

arrived at much the same diagnosis of – and approach to – nanotechnologies as governmental decision-makers in Britain and the United States. Like their British competitors, German companies have not hesitated in their response to the opportunities for influence entailed in the invitation for dialogue and cooperation. Companies and their representatives have taken every opportunity to consult and cooperate with federal authorities, pressing on decision-makers their concerns about scientific developments, technical feasibility and economic impacts. The German policy process is in turn ripe with examples of engagements, informal discussions and collaborations among industry and federal authorities.

Risk Management Strategies and Safety Research Policy

Following a strategic overhaul of innovation policy in 2002, the German government launched the overarching *Nano-Initiative – Aktionsplan 2010* (BMBF 2007) as a stand-alone strategy within the national High-Tech Strategy (BMBF 2006). The action plan outlined measures to bundle cross-departmental and interdisciplinary research in a number of priority areas, including electronics, chemicals, pharmaceuticals and energy; reduce obstacles to innovation and development; invest in early stage training and knowledge transfer; foster cooperation at the international level; identify and mitigate possible human health and environmental risks; explore feasible regulatory mechanisms; and invite dialogue with the public and stakeholders (BMBF 2007: 13f.; 2011a). The action plan commits the Federal Government to the safe and responsible development of nanotechnologies, emphasizing that "[i]t is imperative that we extend our knowledge on the consequences of releasing nanoparticles for the environment and health so that we can better evaluate the potential for harm." (BMBF 2007: 25) Collaborations and dialogue with industry was in this context recognized as important strategic measures to realize this commitment, and have since constituted a consistent priority of federal nanotech policy. Both the Federal Ministry of Education and Research (BMBF) and the Ministry of Economics and Technology (BMWi) have for example initiated sector dialogues to inform companies about the potential of nanotechnologies, fund new lead innovations, and support the uptake of the technology among SMEs. Branch-level industrial dialogues have further served to explain and clarify the opportunities – and risks – of nanotechnologies (BMBF 2007: 15). Dialogue on research priorities and the nature of regulatory controls is thus a defining feature of the policy process in Germany – a feature that has found its most visible expression in the German NanoKommission.

Organized by the Ministry of the Environment, the Federal Government convened the NanoKommission in late 2006. Acting as steering committee for the wider federal NanoDialogue, the NanoKommission involved more than 100 experts and stakeholder

representatives. Discussions within the NanoKommission were intended to foster exchanges among government and stakeholder groups, offer advice and provide inputs to federal decision-makers. Over the course of two dialogue phases – from 2006-2008 and again from 2009-2011 – the NanoKommission was organized around a number of working groups, each consisting of expert members representing environmental and consumer organizations, unions, independent scientists, industry and public authorities. In contrast to many civil society organizations, which expressed some initial reservations, industry readily jumped on the opportunity to engage federal authorities. A former participant recalled: "they were interested [in the dialogue] from the beginning, because they were afraid of the GMO debate […] they were really afraid that the opinion could turn around and then they would have a problem. So they were eager to already in the beginning discuss all these safety issues to not have the problems later on."[29] Unlike the NNI, then, the NanoKommission has in other words served as a 'conduit' through which industry – as well as other stakeholder – views and inputs could flow into the formulation and execution of federal research priorities and activities. Consider Working Group 2 as an illustration.

At its constitutive meeting in March 2007, the NanoKommission asked members representing public authorities, industry and other stakeholder groups to provide an overview of current knowledge about safety issues and risks. Following extensive deliberations, the group drew up a set of physical, chemical and biological properties intended to facilitate comparisons across scientific studies. Members further agreed to a list of criteria indicating 'concern' or 'no cause for concern' as an initial step towards systematic risk assessment of nanomaterials (NanoKommission 2008b; Catenhusen and Grobe 2008). The list was welcomed by the Federal Government as useful guidance for future safety research; and federal decision-makers have since employed the criteria to inform research strategies and priorities (Bundesregierung 2012). With the Federal Government taking the various recommendations emerging from the dialogue process to heart, observes agree that the NanoKommission has left a distinct mark on the direction of German nanotech policy. And German companies and their representatives have thus enjoyed opportunities to shape decisions on research strategies and risk assessment priorities on a level at least comparable to their British competitors.

As in other countries, ensuring a coordinated response has been a priority for the Federal Government (BMBF 2006; 2007; 2011a). For this purpose, the NanoKommission much like the UK NRCG and the U.S. NNI oversaw the coordination of federal departments and their nano-

[29] Interview, Berlin, June 22, 2012.

related investments and policies. Coordination across federal entities with a research mandate for nanotechnologies has further been pursued through inter-ministerial deliberations under the auspice of a BMU steering group. Discussions in the steering group have sought to facilitate intra-governmental information exchange and consensus on open issues to ensure a common nanotech position. The ministerial steering group has at the same time supported lower level discussions among federal agencies.[30] One illustrative output of these discussions is the joint 2007 research strategy on health and environmental risks developed by three federal authorities – the Institute for Occupational Safety and Health (BAuA), the Institute for Risk Assessment (BfR) and the Federal Environment Agency (UBA).

To coordinate and prioritize their activities, the three agencies identified a number of strategic objectives equally important for occupational safety, consumer and environmental protection. In the course of drawing up the strategy, the three agencies consulted widely among representatives from industry and other groups, with a draft version discussed at conference in November 2006 (BAuA, BfR and UBA 2006). Although the outcome of inter-agency deliberations, regular discussions with their respective constituents have nonetheless sheltered the strategy from the criticisms levied against the comparable U.S. NEHI strategies. Rather than viewed as formulated in a 'federal vacuum', the strategy was meant to communicate what from a regulatory perspective was perceived as the most pressing research needs to a broader audience[31] – the strategy for example formed the initial basis for discussion among members of Working Group 2 (NanoKommission 2008b).

With their joint strategy, the three agencies advocated collaboration with industry as a sensible approach to systematically evaluate and bridge existing knowledge gaps. Similar commitments to cooperation abound in other governmental publications, and public-private research partnerships indeed figure prominently in the German approach to enable a targeted response to nanotechnologies. Beyond the three agencies' own research investments and projects, implementation of their joint strategy has relied on the BMBF's funding programs for nano safety research, most notably with the NanoCare cluster projects (NanoCare, INOS, and TRACER). Undertaken in cooperation with industry, the NanoCare projects collectively sought to investigate the potential risks of new nanoscale or nanostructured materials, while communicating the results to affected commercial interests and the public. The largest project within the cluster, the NanoCare consortium, was founded in 2005 as a 50:50 public-private

30 Interview, Dessau-Roßlau, October 8, 2012.
31 Interview, Dessau-Roßlau, October 8, 2012.

partnership. NanoCare was intended to define new and standardized methods for investigating nanomaterials and to generate new data concerning material characterization (NanoCare Project Consortium 2009b: 89). In addition to the manufacture and characterization of new metal oxide nanoparticles, the consortium aimed to establish titanium dioxide and carbon black as reference materials. With the INOS and TRACER projects, NanoCare sought to increase knowledge about the biological effects of nanomaterials as well as standardize analytic procedures (Nau and Krug 2009: 1). NanoCare ultimately delivered important new insights and established several novel methods for characterization and occupational measurements; and the project was ultimately instrumental to Germany's decision of assuming lead sponsorship for titanium dioxide in the OECD process (NanoCare Project Consortium 2009a; 2009b).

Joint public-private partnerships are in short viewed as important enablers of federal risk management strategies (BMBF 2011a: 29). Observes a federal official: "there is an interest from politics to involve the industry in such projects. Because otherwise they would do the [research] and we would never see [the data]. It is also a way of controlling them."[32] Unlike the situation in the United States, industry has however voiced few reservations about partnering with federal authorities. The official offered this explanation:

> "If they develop applications after such collaborations, it will be harder for the federal agencies to criticize these products or these applications, because they would then say: 'well, we had a collaboration together.' So it is very sensible for them to collaborate, because they have their critics within the boat. That's the rationality behind this: 'if we collaborate in the first place or in the early stages, then we won't have the problems later, because then we can say: 'well, you have been in the project or you knew the data and so on.' So this is a way of producing legitimacy for the applications later."[33]

For the authorities, on the other hand, the official emphasized:

> "We would rather take part in such a research project, because otherwise we would never see such data. So in a way, it is true […] that you become dependent upon industry, but on the other side [the agencies say]: 'we take part in this, because otherwise we would never see such data.' We want to give advice since we are in the project and we will talk about the design of experiments, we will talk about the materials that are tested in the experiments and so on. It comes from both sides: industry is not independent and can do what they want."[34]

In marked contrast to the quarrels, which plague questions of agency access to safety data in the United States, the issue is largely uncontroversial in Germany. Not however because companies are less concerned about confidentiality than their American competitors. But

[32] Interview, Berlin, June 22, 2012.
[33] Interview, Berlin, June 22, 2012.
[34] Interview, Berlin, June 22, 2012.

German companies have secured a different – and advantageous – settlement. Joint public-private partnerships do of course increase the amount of information available to federal authorities; but their access to the raw data from joint safety studies is neither automatic nor guaranteed. Hence, officials from UBA explained that to acquire information from joint research projects, the agencies must approach the BMBF. The ministry in turn negotiates the terms of access with the consortium partners. The data is only released if *all* consortium partners consent.[35] The BMBF – traditionally a strong ally of the German chemical industry (Paterson 1991: 237f.; Grant, Paterson and Whitston 1988) – in short acts as gatekeeper. While public funds come with a demand for transparency, the agencies are in effect left with little leverage to convince consortium partners to reveal or share data that could infringe on their commercial interests. Viewed from the strategic risk-benefit calculations of German companies, it is thus hardly surprising, if joint research looks attractive.

Voluntary Reporting Initiatives

As a recurring theme in their joint strategy, the three federal agencies recognized the need to access information and experiences from industry to guide research priorities and assess the adequacy of existing regulatory frameworks. Acknowledging corporate concerns over confidentiality, the research strategy identified dialogue as a crucial means to encourage manufacturers and industrial users to volunteer information on materials characterization, production volumes, use patterns, *et cetera* (BAuA, BfR and UBA 2007). Despite their joint statement, however, the three agencies have in effect adopted different positions on how to convince companies to disclose information – with mixed experiences and outcomes as a result. In the United States, the diverging experiences of NIOSH and EPA can be attributed to corporate reluctance to incur regulatory liabilities. In Germany, however, corporate decisions to disclose or withhold information owe less to any inherent discomfort in cooperating with federal authorities. Rather we must look to variations in how officials have sought to accommodate corporate interests. The mixed experiences with data sharing in turn reflect more deep-seated differences in how the federal agencies interact with their industrial constituents; a conclusion again best illustrated in relation to worker and environmental protection.

With the aim of collecting information on the manufacture and handling of nanomaterials at work, the Federal Institute for Occupational Safety and Health in collaboration with the German Chemical Industry Association, VCI, conducted a joint survey on occupational health and safety

[35] Interview, Dessau-Roßlau, October 8, 2012.

measures from 2006 to 2008. Based in part on a consensus emerging from two stakeholder conferences in September and October 2005 (VCI 2005; Löchtefeld and Claus 2005), the need for and design of the questionnaire was discussed and agreed among representatives from BAuA and VCI. Prior to the survey, a small group of companies went over the questions to ensure, as a VCI representative noted, "are these the correct questions, can we answer them at all and do they make sense."[36] The survey collected information on the number of companies producing, using and processing nanomaterials, the types and volumes of nanomaterials in production and the number of workers involved. The survey further sought an overview of occupational health and safety methods applied in the chemical industry. To facilitate participation, questionnaires were returned to and anonymized by VCI before the data was delivered and evaluated by BAuA (BAuA 2008: 1). 217 companies responded to the questionnaire. Compared to the limited participation in the VRS and the NMSP – 13 and 29 submissions during their respective two year operations – the joint BAuA-VCI survey would appear 'astonishingly' successful: quantitatively, this is correct, although the results probably owes more to differences in program design. Since the questionnaire addressed mostly issues of use patterns and risk management practices – information readily available to companies – filling in the questionnaire was less cumbersome than meeting the submission criteria under the VRS or the NMSP. In contrast to the VRS, for example, which requested detailed information on properties, behavior measurements and detection techniques, the survey thus only sought relatively basic information.

The survey did nonetheless ask some questions, *e.g.* on chemical identity, which might conflict with commercial confidentiality. Procedures for handling sensitive data were consequently negotiated among BAuA and VCI representatives, with the association in turn assuming the role of interlocutor between agency and companies. On the conduct of the survey, a VCI representative observed: "We compiled this and made it anonymous. We just said this and this substance [is produced], but you could not relate it to the companies. [This ensured that] there is not one company that knows what the others are producing and what kind of results they have – this is guaranteed!"[37] A BAuA official elaborated: "we have a contract with industry that we don't [publish] detailed information […] because industry has a very, very deep fear that data will get to the public, especially when they tell us what substances they are working on, how much they produce and use in special fields. So we have a very, very complicated way to collect the data."[38]

36 Interview, Frankfurt, October 11, 2012.
37 Interview, Frankfurt, October 11, 2012.
38 Interview, Dortmund, October 11, 2012.

The official emphasized: "It is our idea of working [with industry] that we promise anonymity, if it is wanted. We can keep confidentiality, it is our business […] We promised it with the [survey, because] they said: 'we want to be sure that the data can't go out' and so we have separated it."[39] German companies in other words share the 'deep fear' of disclosure with their U.S. competitors. Rather than resist disclosure, however, companies could confidently rely on the vigilance of their association. The VCI in turn exercised significant control on the execution and overall design of the questionnaire, with the association and its members in effect able to decide the range of questions included in the survey.

BAuA has – much like NIOSH – successfully employed partnerships with industry to gain a better understanding of actual work practices, exposure controls, and risk management routines. As a VCI representative recalled: "BAuA wanted to know what companies are doing with nanomaterials and also to know what kind of safety features they put in and what experience they had in workers medical surveillance."[40] Concerning the VCI's role, the representative observed: "If they ask us, we typically [help them]. In the U.S., companies go to court and sue them. But we typically do this, because we say that is in the end of help [to us]."[41] For industry, the value of the survey has most evidently been the publication of a number of guidance documents. During initial discussions, BAuA and VCI representatives agreed the need to develop best practice guidance, including recommendations and operating instructions for companies working with nanomaterials. As a result, and based on information collected in the survey, VCI published the joint *Guidance for Handling and Use of Nanomaterials at the Workplace* (BAuA and VCI 2007) in 2007. Combined with the more general report *Responsible Production and Use of Nanomaterials* (VCI 2008), these guidance documents provide detailed recommendations on worker protection as well as guidelines for regulatory compliance and risk assessment. Like NIOSH, then, partnerships with industry have yielded important inputs to the development of safety guidance. Unlike NIOSH, however, BAuA *does* have a regulatory mandate. Hence, the agency's capacity to encourage voluntary disclosure cannot be explained by the absence of regulatory liabilities. Rather, ongoing dialogue with industrial stakeholders and accommodation of corporate interests has allowed BAuA to persuade companies to volunteer information – a conclusion further illustrated by the difficulties experienced by the Federal Environment Agency.

39 Interview, Dortmund, October 11, 2012.
40 Interview, Frankfurt, October 11, 2012.
41 Interview, Frankfurt, October 11, 2012.

UBA has variously sought to encourage industry to report information on a voluntary basis, appealing for "companies engaged in manufacturing and trade [to] submit any information available on the behaviour of nanoparticles with regard to possible exposure and their fate in the environment." (UBA 2006: 15) Prior to 2006, UBA further expressed interest in a voluntary reporting scheme (BAuA, BfR and UBA 2006). Based in part on the disappointing experiences with the VRS and the NMSP, a voluntary initiative was however never implemented. But politics also stood in the way. Reflecting on the barriers to a voluntary scheme, one agency official noted: "UBA wouldn't just start it without the consent at least of the BMU and the BMU wouldn't do it without the consent of the other ministries."[42] Supplements another official, "and the other ministries thought it was senseless."[43] UBA thus failed to secure a political sign-off on a voluntary initiative; and neither have appeals for disclosure generated the response the agency had hoped for. UBA officials instead turned their attention towards statutory instruments.

In 2009, the agency urged the introduction of a mandatory registration requirement, arguing that the German Chemicals Act contained the necessary statutory authority (Becker *et al.* 2009: 19). UBA next persuaded the BMU to commission a legal feasibility study of a nanoproduct register. Co-authored by UBA, the study concluded that "[a] register of nanoproducts (nanomaterials, mixtures and articles) produced or placed on the market in Germany is legally viable and is workable in practice." (Hermann and Möller 2010: 9) In the ensuing debate, UBA argued that a mandatory register was needed to ensure access to reliable data and thus enable an immediate response should hazards to human health or the environment be discovered (NanoKommission 2010c). A voluntary registration commitment was in contrast rejected, since it was unlikely to generate needed information and further would leave authorities without the possibility of 'applying coercive measures or imposing sanctions' to compel data disclosure (Hermann and Möller 2010: 75). Although a nanoregister won little political favor, UBA's experience in short mirrors that of U.S. EPA: despite initial appeals for voluntary disclosure, scant interest from industry ultimately led the agency to embrace mandatory instruments.

What lessons should we draw from the diverging experiences of BAuA and UBA? We must of course recognize the different nature of data sought by the two agencies: whereas companies learn from experience of working with their materials, they do not necessarily know their

42 Interview, Dessau-Roßlau, October 8, 2012.
43 Interview, Dessau-Roßlau, October 8, 2012.

environmental effects or fates.[44] Convincing companies to volunteer information about use patterns, production volumes or risk management procedures requires less effort than persuading them to disclose proprietary information on the characteristics of their materials. This was the situation facing NIOSH and EPA as it did BAuA and UBA. The roots of the diverging views and preferences of the two agencies run deeper, however. BAuA enjoys a long tradition of dialogue and cooperation with its industrial constituents. On the issue of reporting, a BAuA official noted:

> "We have different views [among the agencies], and from the view of occupational safety and health we say: 'the companies know what they are doing, that's okay', and the survey helped us get an idea on a more general level of what they are doing, and that is enough for us. But if you [look to] the environmental people or the people who are protecting consumers, they say that we need a register."[45]

UBA's relationship with industry has in contrast traditionally been more uneasy (Grant, Paterson and Whitston 1988: 285f.; Paterson 1991: 231); and, the agency has indeed time and again found itself in opposition to the VCI and other industrial interests on the direction of German nanotech policy (See *e.g.* UBA 2006; VCI 2011; NanoKommission 2010c). While agency officials claim that relations with industry have improved,[46] one observer noted,

> "with worker protection there has been a long history of cooperation between the agency and industry [but] there is not such a tradition […] with the environmental agency. It is rather the situation […] that industry often sees the environmental administration as being in opposition to them and *vice versa* as well – so they don't get along that well."[47]

Faced with few compelling incentive to volunteer safety data, and with no interlocutor to facilitate dialogue and cooperation among the agency and companies, it is perhaps to be expected that UBA – like U.S. EPA – looks to create those incentives by mandatory instruments. Unlike EPA, however, UBA's regulatory mandate is relatively limited. Rather than any inherent discomfort in sharing information with federal authorities, industry's reluctance to work with UBA stems more from misgivings in the agency's agendas and intentions.[48]

Regulatory Relationships in Germany

What emerges from this account of German nanotech policy is thus a general pattern of close and collaborative interactions among federal entities, German companies and their representatives. Early recognition of the need to understand public aspirations about

44 Interview, Dessau-Roßlau, October 8, 2012.
45 Interview, Dortmund, October 11, 2012.
46 Interview, Dessau-Roßlau, October 8, 2012.
47 Phone interview, October 30, 2012.
48 Phone interview, October 30, 2012.

nanotechnologies, industry drivers and the concerns of NGOs (BMBF 2002; Paschen *et al.* 2003; Anton *et al.* 2005) prompted federal decision-makers to embrace a strategy of ongoing dialogue. Although the German NanoKommission may represent a unique organizational format to address the regulatory challenges of nanotechnologies, the extent and nature of consultations, engagements and policy deliberations are nonetheless comparable to the situation in Britain. Federal authorities have actively sought the advice and views of industry on all major policy initiatives. Regular discussions have facilitated a range of collaborations, covering joint contributions to safety research, exposure mitigation and the development of risk management methodologies. Dialogue and cooperation with industry has in turn served as important enablers of the federal government's regulatory ambitions for nanotechnologies.

Participation in the NanoKommission and various other decision-making bodies have provided channels through which industry views and inputs could flow into the formulation and execution of federal nanotech policies and research initiatives. Regular consultations and informal deliberations have in turn allowed industry to leave a distinct mark on the development of German nanotech policy. Like their UK competitors, industry representatives have sought to nurture and reinforce cooperative relations with regulators, resulting in extensive discussions, accommodation of corporate interests and broad, if not universal agreement on the direction of German nanotech policy. While UBA's failure to encourage disclosure does distort this general picture, it also stands relatively isolated. UBA's experience however closely resembles the Danish nanotech story.

REGULATING NANOTECHNOLOGIES IN DENMARK

The regulatory process in Denmark has seen state authorities pursue a range of strategic measures and policy initiatives that by now will be familiar to the reader. Like their American and European peers, governmental decision-makers have committed considerable resources to address the uncertain risks of nanomaterials; and to guide the direction of Danish nanotech policy, state agencies have similarly prioritized initiatives to canvass the views of stakeholders. Ensuring the safe and responsible development of nanotechnologies has in short entailed a comparable commitment to dialogue and collaboration. Similar to the situation in the United States, however, cooperation among state authorities and industry never materialized. Despite an invitation for dialogue, Danish companies have been reluctant to pursue the strategies of their German and British competitors. With little notable industry mobilization, the Danish policy process has in consequence been dominated by state authorities – and the prevalence of irregular

and *ad hoc* engagements among officials and industry representatives. Although they have left little mark on Danish nanotech policy, companies and their representatives have nonetheless welcomed governmental initiatives and strategies. Even as a political agreement was concluded in 2012 to introduce a mandatory nanoproduct register, business representatives have voiced few loud objections or protests. Acquiescence and adaptation to governmental policies are in short words that best describe the response of Danish industry.

Risk Management Strategies and Safety Research Policy

In October 2004, a broad political agreement named nanotechnology a priority of national science, technology, and innovation policy. Parallel to discussions in Parliament, a steering group established under the Ministry of Science, Technology and Development undertook a foresight exercise on Danish nanoscience and technology, culminating in the publication of an action plan in December 2004 (Ministeriet for Videnskab, Teknologi og Udvikling 2004). To ensure that Denmark derive maximum economic, environmental and societal benefits from nanotechnologies, the action plan called, first, for a significant boost in research funding; accompanied secondly by measures to promote training and knowledge transfer to ensure that future breakthroughs translate into product and market opportunities. The action plan further called for a coordinated strategy across ministerial departments and agencies to avoid unnecessary duplication of efforts. While primarily focused on the potential benefits of nanotechnologies, the action plan also noted the existence of new and partly unknown risks. To mitigate these risk uncertainties, the action plan urged collaboration among state authorities, research institutions and industry. The Ministry of the Environment was encouraged to assume the lead on promoting dialogue with the aim of indentifying and closing knowledge gaps, guide future research initiatives and enable an effective response to possible human and environmental risks (Ministeriet for Videnskab, Teknologi og Udvikling 2004: 37).

In response to the action plan and recommendations made by the Danish Board of Technology (Teknologirådet 2006), governmental decision-makers since launched a range of policy measures that mirror public responses in other countries. State authorities have sponsored various initiatives to expand the evidence base, fund safety research and promote international cooperation. Coordination across governmental agencies, research institutions and university centers is facilitated through an informal network of civil servants and academic researchers organized by the Danish EPA, Miljøstyrelsen (MST). The network was established to inform research priorities by collecting, interpreting and disseminating experiences with risk assessment and management of nanomaterials. Coordination, dialogue and cooperation thus constitute consistent priorities of Danish nanotech policy; and decision-makers and regulatory authorities

have in short embraced a comparable diagnosis of – and approach to – nanotechnologies as their peers in other countries. It is rather when we look to the response of industry that the Danish policy process stands out.

Danish companies and their representatives have played little or no role in either of the research initiatives or policy discussions undertaken by state authorities since 2004. Although open to non-governmental experts, industry representatives for example never joined MST's coordination network. There have been few regular contacts among state authorities and industry and no ongoing dialogue to inform the direction of Danish nanotech policy. Discussions have instead occurred on a largely *ad hoc* basis: individual companies have on occasion approached MST to voice their concerns; but as an official emphasized these contacts have primarily been motivated by a desire to clarify their responsibilities and learn about international developments.[49] Although companies have sought information from state authorities, they have offered few inputs in return.

Beyond such informal, but irregular contacts, the policy process in Denmark has seen issue-specific conferences and occasional consultations among public authorities, industry representatives and other stakeholder groups. In November 2007, for example, MST with the Danish Chamber of Commerce and the Confederation of Danish Industry hosted an open workshop for industry, NGOs and other stakeholders (Miljøstyrelsen 2007).[50] Although welcomed by industry representatives as an opportunity to exchange views and promote mutual understandings,[51] the broad contours of Danish nanotech policy had nonetheless coalesced *before* the workshop. According to a MST official, the workshop thus did little to change or influence agency policies or priorities.[52] In contrast to *e.g.* the NanoKommission, the workshop was in fact not intended to inform the direction of Danish nanotech policy by canvassing the views stakeholders. It served instead primarily as a vehicle to communicate regulatory initiatives and international developments to a wider audience.

While state authorities have consulted broadly on all major initiatives and called a number of orientation meetings, their policies, priorities and designs have not taken shape through an dialogue with industrial stakeholders. Policy initiatives and strategic measures have instead been informed and decided through inter- and intra-agency deliberations. The 2010 adoption of a new national chemicals plan illustrates: drawn up by MST officials, the action plan restates previous

49 Interview, Copenhagen, March 9, 2011.
50 The workshop was held as part of *Kemikaliedag*, a yearly reoccurring stakeholder event in the chemicals area.
51 Interview, Copenhagen, March 9, 2011.
52 Interview, Copenhagen, March 9, 2011.

commitments to nanotechnologies, calling for an intensification of national and international efforts to identify and manage potential human health and environmental risks (Regeringen 2010). Prior to drafting the action plan, MST called an orientation meeting to discuss potential priorities and elements. The agency again circulated an updated draft to stakeholders before introducing the plan in Parliament. While stakeholders thus were encouraged to offer their views, an industry representative remarked that the final plan ultimately had changed little from initial drafts.[53]

Policy strategies and initiatives have in short been drawn up by officials without prior discussion – and only then been communicated to external stakeholders. Rather than cater to the interests of Danish industry, the 2010 chemicals plan for example reflects a mix of administrative interpretations, conclusions and evaluations of nanotech, general chemical safety considerations, and a set of specific political circumstances.[54] Observers have thus suggested that nanotechnologies were prioritized in response to growing political attention – and that the action plan was primarily meant to anticipate demands for further national initiatives by demonstrating a clear governmental commitment to nano safety.[55] Whether or not political contingencies did indeed persuade MST is an open question – the push to include nanotech however did not originate with industry. An MST official observed:

> "The Confederation of Danish Industry […] is where you would turn for an industry view on nano. Aside from *Kemikaliedag* [the stakeholder workshop], however, I cannot recall an issue where they voiced an opinion. They voice opinions about endocrine disruptors or chemicals in general, but I actually cannot recall an occasion where they voiced an opinion on nanotechnology – which perhaps simply reflects that the issue has been uncontroversial so far."[56] (*My translation*)

Since they have voiced few opinions and demands, Danish companies have in effect left all major decisions to state authorities. Looking to the implementation of strategic research initiatives and safety studies, we find much the same pattern. Following recommendations made in the 2004 action plan, grant authorities have prioritized research focused on the toxicity, epidemiology, and bioaccumulation of manufactured nanomaterials, with additional funding allocated to support the development of risk management methodologies and instrumentation. Internationally, the Danish Agency for Science, Research and Innovation closely monitors ongoing developments in the OECD and the EU with a view to guide national research initiatives. Through the Nordic Council of Ministers, Denmark has initiated and co-funds the

53 Interview, Copenhagen, March 9, 2011.
54 Interview, Copenhagen, March 9, 2011.
55 Interview, Copenhagen, March 9, 2011.
56 Interview, Copenhagen, March 9, 2011.

Nordic contribution to the OECD Sponsorship Program. National research institutions and universities have meanwhile established permanent research groups and centers, which link to international programs. Since 2005, the National Research Centre for the Working Environment, NFA, has for example housed a research group focused on occupational health and safety aspects of nanomaterials. With the aim of strengthening and consolidating NFA's activities, the 2012 national budget established a Danish Nano Safety Centre. Beyond its own in-house safety research, the Centre intends to collect and disseminate international scientific results among state authorities and national stakeholders. The Centre further targets commercial users of nanomaterials to ensure that they have access to comprehensive information about potential risks in their products and manufacturing processes.

Although the Danish Nano Safety Centre signals a commitment to knowledge exchange, examples of joint public-private research partnerships are rare. In part because Danish authorities have not encouraged joint research ventures on a scale similar to *e.g.* the German NanoCare projects, industry has made few direct contributions to government-sponsored safety studies, and reactions to calls for collaborations have been mixed. Some NFA research projects have been co-sponsored by industry, but only through financial commitments to research carried out by university or governmental researchers – corporate experts and scientists have not participated directly.[57] The Danish Coating and Adhesives Association has for instance agreed to act as joint sponsor of a toxicity and exposure study undertaken by the NFA. Test materials were selected in collaboration with representatives from industry, who agreed to supply industrial samples (Saber, Wallin and Vogel 2011). The scope of joint research ventures in Denmark is thus more reminiscent of the situation in the United States than comparable German or British initiatives. Unlike the NanoCare, PROSPEcT or NanoRelease projects, however, industrial sponsors had no say in how the study was designed or reported. Questions of design, methodology and reporting were instead decided exclusively by NFA researchers. Nonetheless, data access and ownership never emerged as an issue.[58]

But why would the association and its members agree to finance a study over which they had no control? There is a straightforward reason for this: the application of nanotechnologies by the Danish coating industry relies on nanomaterials imported from international manufacturers (Tønning and Poulsen 2007). As industrial users of nanomaterials, the stakes of corporate sponsors in the materials in question are minor relative to the companies that manufacture them.

57 Phone interview, July 2, 2013.
58 Phone interview, July 2, 2013.

Adverse results – which might inflict serious harm on the commercial interests of the producer – would not to a comparable extend be deemed problematic for the association and its members. In fact, learning about possible adverse effects – unknown to the users and perhaps only vaguely apprehended and therefore not communicated by the manufacturer – would allow corporate sponsors to undertake protective measures, anticipate future restrictions or if necessary look for substitute materials. More than a vested interest in their materials, worker protection was in other words the primary motivation of corporate sponsors. The procedure – industrial samples provided anonymously through their association – meanwhile meant that individual sponsors would be sheltered from negative publicity should hazards for their contributions be discovered.

Safety research in Denmark has in short only to a limited extend been informed by the commercial interests and experiences of industry. Rather the direction of safety research has been defined by the interests of university researchers and government experts.[59] This is not to diminish the value of government-funded research in Denmark: indeed, university researchers and research institutions have made important contributions to the global safety assessment of nanomaterials. What these efforts only to a lesser extent have achieved is to assess business-related needs with respect to nanotechnologies. Research institutions and regulators have on occasion engaged corporate representatives in dialogue and cooperation; yet on the whole decision-makers have been unable to tap current experiences from industry or information on the state of applied research.[60]

Voluntary Reporting Initiatives

Spurred by the April 2006 MagicNano incident,[61] MST commissioned two projects to gain an overview of industrial uses of nanomaterials in Denmark and assess information on consumer exposure. The first of these projects, mapping nanomaterials in consumer products, was finalized in spring 2007. The report identified 243 nano-enhanced articles and products on the Danish market. For most products, the report was however unable to verify concentration levels or obtain documentation of material properties (Stuer-Lauridsen *et al.* 2007: 9). The Danish Technological Institute meanwhile conducted a survey of industrial production and use of nanomaterials. The survey sought information on applications of nanomaterials in Danish

59 Interview, Copenhagen, June 1, 2011.
60 Interview, Copenhagen, June 1, 2011.
61 In April 2006, the German Federal Institute for Risk Assessment issued an immediate recall of two nano-enhanced products that allegedly had caused close to one hundred reported health incidents. Paradoxically, the agency eventually concluded that MagicNano did not contain any nano-sized particles.

industry, current risk management measures and waste disposal practices. A questionnaire was circulated among 165 companies, which in different contexts had expressed an interest in nanotechnology (Tønning and Poulsen 2007). The two projects were intended to assist MST determine levels of exposure, collect information on the manufacture and handling of nanomaterials and inform considerations on appropriate regulatory controls.

With similar projects undertaken in 2011 and 2012 (Mikkelsen *et al.* 2011; Tønning *et al.* 2012), MST has demonstrated much the same interest in convincing companies to volunteer information as authorities in Britain, Germany and the United States. MST however launched these initiatives without prior discussion of the need for or design of the surveys. The projects were instead commissioned with consultants and industry views were not considered in their formulation and implementation. The market survey for example merely screened existing product databases, but did not directly engage producers or retailers. Although the survey thus did produce a market overview, it generated little additional information. For most products, the authors were unable to access information on concentration levels or the chemical identity of the nanomaterials in question. Acknowledging that the results likely underestimate the number of products in commerce, the report in part attributed the difficulties encounter by the project team to the absence of an industry intermediary that could have assisted in identifying and convincing companies to divulge product information (Stuer-Lauridsen *et al.* 2007: 69). As the project team discovered, producers and retailers were in fact not exactly forthcoming in sharing information about their products and activities. By way of contrast, consider comparable German attempts to improve knowledge about the occurrence of nanomaterials in household products.

Prior to 2006, BfR expressed similar interests in a market survey (BAuA, BfR and UBA 2006: 6f.). Talks with industry representatives however dissuaded the agency from further pursuing this course.[62] BfR instead engaged experts from industry and other stakeholder groups to identify nanomaterials already used in food, cosmetics, surface coatings and textiles – or likely to enter commerce in the near future. Feedback from these discussions in turn helped the agency identify sources of exposure, anticipate future development trajectories in food and other consumer products, and thus informed its strategies to mitigate potential risks (Zimmer, Hertel and Böl 2010a: 25). While the Danish mapping initiatives provided regulators with a market overview, they did little to improve their understanding of how the uses of nanomaterials and the number of consumer products might develop. Hence, by the time MST conducted a second

[62] Interview, Berlin, June 22, 2012.

survey in 2011, the authors – using the same method – found that the number of nano-enabled product had increased by almost 300 percent (Mikkelsen *et al.* 2011). Contrasting MST's 2007 industrial survey with the joint BAuA-VCI survey further illustrates the diverging responses of German and Danish companies to appeals for voluntary disclosure.

Although the two reporting instruments at surface value are comparable, their similarities disguise important, if subtle, differences in how regulators have sought to encourage companies to volunteer information. With the aim of collecting information on the handling of nanomaterials in a workplace setting, BAuA as we saw above engaged the VCI as interlocutor. Ongoing dialogue with VCI representatives and accommodation of corporate concerns in turn helped BAuA persuade companies to volunteer commercially sensitive information. MST sought no such dialogue with Danish business representatives. Although various trade associations were contacted in an attempt to identify potential participants (Tønning and Poulsen 2007: 26f.), the final list of recipients for the questionnaire were drawn up based on existing registers and inputs from university researchers. The questionnaire itself was designed in collaboration with research institutions, but without prior consultation of industry. No procedure for anonymity was agreed and MST did not explicitly spelled out how and for what purposes information might be used (Tønning and Poulsen 2007). MST in short demonstrated little explicit appreciation for potential corporate concerns. The agency instead limited the extent and nature of information requested from industry.

Recall that issues of *e.g.* chemical identity were of major concern to German companies; and that the active participation of the VCI and extensive deliberations among representatives from BAuA and industry allowed the agency to convince companies to report such information. In Denmark, such challenges were avoided – by excluding questions on chemical identity from the survey. The Danish survey instead only sought information on the *class*, not identity of nanomaterials used by industry. Although MST thus did gain access to information on commercial applications and risk management practices, important knowledge gaps persisted. Hence, knowing that specific branches of industry work with nanoparticles is obviously important for risk management. Should hazards be discovered for *specific* nanomaterials, however, information about *classes* of nanomaterials will not suffice to mitigate potential exposures. If for example the risks of say nano-silver were deemed sufficient to justify a regulatory response, only knowledge about where, how and for what purposes nano-silver is used would allow MST to take action to control human and environmental risks. It is of course difficult to say how Danish companies would have responded had MST requested information about the identity of their materials. Based on UBA's experience, a qualified guess would however emphasize that since

MST did not discuss the need for, design and purpose of an industry survey with manufacturers and users, the agency would have found it difficult to persuade companies to divulge sensitive information.

What we can say with relative confidence, though, is that the results of the survey were not picked up by Danish industry: because MST neglected to – or could not – secure the active support of industry representatives in the implementation of the reporting exercise, there was no interlocutor to act on the results as the basis for formulating guidance documents. Although the Industrial Occupational Health Committee, I-Bar, published such guidance in 2011 – independent of the survey – Danish companies meanwhile had to look to the authorities to clarify the extent of their regulatory responsibilities. MST has however prioritized measures to map the existence and application of nanomaterials over attempts to formulate guidance documents. The Danish Working Environment Authority, Arbejdstilsynet, likewise did not issue statements on nanomaterials until May 2013. The industrial survey in short did little to establish or explain the industry standard of care – nor for that matter assist companies working with nanomaterials minimize potential risks to their workers.

Dialogue and collaboration with industrial stakeholder helped convince BAuA that no further reporting measures were required. MST drew different lessons. Although initially satisfied with what the agency learned from its various surveys and mapping initiatives, the story of data sharing in Denmark does not end here. Instead and much to the dismay of industry, the 2012 national budget saw the conclusion of a narrow political agreement on a mandatory nanoproduct register. Passed as an amendment to the Danish Chemicals Act in March 2013, manufacturers and importers will from 2014 be required to register their products and available information with MST. The experience with voluntary reporting in Denmark thus led MST to draw conclusions that parallel those of U.S. EPA and UBA. Despite initial interests in voluntary reporting, meager results and scant industry participation ultimately convinced the agency that mandatory requirements were necessary. Where the experience of regulators in Denmark does diverge from their colleagues in the United States and Germany is however that MST's limited capacity to persuade industry to divulge information convinced the agency's political principals that a new legal mandate was required. For Danish companies, the outcome of the policy process was thus – for the time being – an unhappy one.

Regulatory Relationship in Denmark

The Danish nanotech story is in comparative perspective at once familiar and distinct: familiar in the policies and priorities of its government; but distinct by the acquiescent and subdued response of industry. State authorities have allocated considerable resources to address

uncertainties about the ecological behavior and toxicological properties of nanomaterials; and in support of these activities, governmental agencies have urged cooperation among all relevant stakeholders. With the exception of a political agreement to introduce a mandatory nanoregister, governmental strategies and initiatives in short mirror public responses in other countries. Where the Danish nanotech experience does stand out is however in the role and response of industry to the invitation for dialogue and cooperation. The policy process has witnessed little industry mobilization to influence the direction of Danish nanotech policy. Decisions on priorities, strategies and initiatives have in consequence been the rather exclusive domain of state authorities and their contacts among governmental experts and university researchers. The Danish policy process is thus characterized by *ad hoc* engagements, informal, but irregular contacts and arm's length relations among regulators and companies. While information has been exchanged among stakeholders in Denmark, this exchange is better characterized as a monologue than a dialogue. State authorities have communicated their preferences, agendas and initiatives to industry. Companies have sought this information to clarify the extent of the responsibilities and anticipate future developments; but they have voiced few demands and offered little input in return. Because industry has played no discernible role in the policy process, with regulators instead relying on their own in-house capabilities and external consultants to inform risk management decisions, companies have in short left little mark on Danish nanotech policies.

Despite a preference for informal contacts, relations among state authorities and industry have thus remained detached and arm's length. The Danish nanotech story is however not one of antagonism, conflict or even deep-seated distrust of state authorities. Chemical safety policy in Denmark is governed by consensus and consultation of affected interests. Observes a MST official:

> "We do of course talk to one another. We consult the full range of views – the trade associations, the unions, the environmental groups, the consumer organizations. Since we have this *Kemikaliedag* [the stakeholder event] as a recurring and common event, we find it easier to interact and communicate. It helps build trust and we are I think therefore able to discuss things in an altogether more fruitful way."[63] (*My translation*)

Concurs an industry representative: "We are of course aware that we have different backgrounds and different interests, but we also share a reasonable level of respect for the professionalism of the others […] *Kemikaliedag* means that we meet regularly – so we know each other and work

[63] Interview, Copenhagen, March 9, 2011.

Table 3.1 American and European Nanotech Policies and the Role of Industry in the Regulatory Process

	BRITAIN	UNITED STATES	GERMANY	DENMARK
Regulatory Strategy	Encourage cooperation	Encourage cooperation	Encourage cooperation	Encourage cooperation
Risk Management Strategies	Informed by extensive industry inputs	Formulated with limited industry inputs	Informed by extensive industry inputs	Formulated with limited industry inputs
Consultation Mechanism	Informal policy discussions	Public consultations Open workshops	Informal policy discussions	Public consultations Open workshops
Joint Safety Research Ventures	Multiple	Few	Multiple	Few
Scope of Ventures	Comprehensive: Full characterization of analyzed materials	Narrow: Release and exposure scenarios	Comprehensive: Full characterization of analyzed materials	Narrow: Passive industry support
Participation in Reporting Initiatives	Limited	Mixed	Mixed	Negligible
Design of Initiatives	Agreed with industry	Decided by officials	Agreed with industry	Decided by officials
Nature of Safeguards	Informal guarantees	Legal provisions	Informal guarantees	None
Regulatory Relationships	Close Cooperative	Detached Arm's length	Close Cooperative	Detached Arm's length
Frequency of Contacts	Frequent Regular	*Ad hoc* Irregular	Frequent Regular	*Ad hoc* Irregular
Conduct of Contacts	Informal	Formal	Informal	Informal
Summary of Business Response	Disclosure	Nondisclosure	Disclosure	Nondisclosure
Nature of Industry Influence	Direct	Indirect	Direct	Negligible

together with everything that entails."[78] While relations among stakeholders in the Danish chemicals sector thus resemble the situation in Germany – with the nanotech debate undertaken by a small group of 'usual suspects'[79] – the nature of their exchanges nonetheless differ. A MST official sums up the situation: "The business associations have not voiced major views on nano – so perhaps they are simply satisfied with our [approach]." (*My translation*)

CONCLUSION

Upon assuming the regulatory challenge of nanotech, governments in America and Europe confronted a number of immediate and intricate problems arising from the uncertain and ill-understood nature of the technology. Guided by what can best be described by an ambition of 'getting it right', authorities in Britain, Denmark, Germany and the United States embarked on a regulatory path intended to ensure the safe and responsible development of nanotechnologies. The scope of their regulatory initiatives, investments and policies are nuanced only by slight differences, and it is thus the commonalities of government responses which stand out from the analysis. But while the political reactions to the uncertain risks of nanomaterials are largely comparable, industry responses differ remarkably: whereas UK and German companies have pursued a course of close, informal collaboration with governmental officials, their U.S. and Danish competitors have in contrast been reluctant to cooperate with regulators; relations among regulatory authorities and industry in the United States and Denmark have instead remained detached and arm's length. Table 3.1 presents a tabular overview of governmental risk management strategies in the four countries, the role of companies and their representatives in policy process, and the character of relations among state authorities and industry. As is evident from the preceding analysis, companies in these four countries have displayed manifest and systematic variation in their inclination to volunteer information to state authorities. Why the reactions of U.S. and UK companies differed is the subject of the next chapter, while chapter five recounts the roots of the varied responses of German and Danish companies.

78 Interview, Copenhagen, March 9, 2011.
79 Phone interview, July 2, 2013.

CHAPTER FOUR

Alternative Routes to Influence: The Politics of Nanotech Regulation in Britain and the United States

Conventional wisdom would lead us to expect that industries in liberal market economies should react alike to similar state policies. Confronted with comparable governmental preferences and strategies, U.S. and UK companies have nonetheless responded remarkably different: dissociation from regulatory decision-makers in the United States and close, informal cooperation with government officials in Britain. The different reactions of American and British companies are in short puzzling and invite a closer inspection of the institutional drivers of business strategies in the two countries. I contend that the varied responses of UK and U.S. companies result from variations in how their political systems concentrate or diffuse regulatory power and authority. Disengagement from regulators in the United States and cooperation in Britain are in turn business responses that grow from the distinct opportunities for influencing regulatory decisions and policies on either side of the Atlantic.

In areas of high scientific and technical uncertainty, such as nanotechnologies, new information can exercise significant influence on regulatory agendas, priorities and policies. This can work in industry's favor, if disclosing information succeeds in convincing state bureaucrats to make decisions that benefits industry. But disclosure is also a dangerous course for industry: while regulators certainly appreciate information volunteered by industry, they may value the information differently than originally anticipated. Companies will therefore only volunteer information to state bureaucrats if they are confident that it will not be used to the detriment of their interests. Companies use their understanding of how formal institutions and their operating procedures structure regulatory action to anticipate the probable responses of state authorities; and how withholding or disclosing information might serve to guide the direction of regulatory politics. Whether companies will decide to disclose, bias or conceal information depends in short on the expected behavior of their regulatory adversaries and the nature of their commitments.

The varieties of capitalism literature suggests that the credibility of governmental commitments is systematically linked to their policy-making powers. Whereas dispersion of

decision-making authority promotes the stability and hence predictability of government policy, concentration of state powers in the political executive breads uncertainty and undercuts the credibility of governmental commitments (Hall and Soskice 2001: 48; Wood 2001: 259). In contrast to this view, I argue that concentration of regulatory authority in state bureaucracies can create the critical impetus for cooperation. Independent state authorities are not easily swayed by changing political and economic conditions, but focus instead on achieving their statutory objectives. Limits on political interference or judicial scrutiny may therefore convince manufacturers that a commitment to pursue a set of stable and predictable policies is credible. Since information and expertise is the most relevant currency in convincing state bureaucrats, concentration of regulatory powers can create potent incentives for companies to divulge information, if this can be exchanged for influence over administrative decisions and policies. Fragmentation of regulatory powers in contrast undermines the credibility of bureaucratic commitments. Litigation or political intervention motivated by appeals from competing interests can compel state bureaucrats to sudden reversals in policy. Uncertainty regarding the future behavior of state bureaucrats reduces the value of cooperation as benefits are either doubtful or unknown. But diffusion of regulatory powers also creates alternative routes for companies to influence regulatory outcomes by convincing other state actors to intervene on their behalf. As the possibilities to obstruct regulatory decisions proliferate, the incentives to divulge information to the agencies responsible for regulating their conduct decline.

In pursuing this argument, the chapter falls in three parts. A first section presents the backdrop for nanotech regulation in Britain and the United States by introducing their respective chemical control regimes. In sections two and three, I connect the different responses of American and British companies to the distribution of regulatory powers in their political systems. I demonstrate how the autonomy of administrative authorities to pursue regulatory policies, insulated from pressures originating from other branches of government, determines their capacity to commit to predictable outcomes; and how the distinct nature of bureaucratic commitments in the two countries weighs on business incentives to volunteer information to state authorities. A final section concludes.

ORGANIZING FOR CHEMICAL SAFETY IN AMERICA AND BRITAIN

In the United States, the control of chemical hazards is primarily the responsibility of the Occupational Safety and Health Administration and the U.S. Environmental Protection Agency. Under the Occupational Health and Safety Act, OSHA is responsible for defining and enforcing

exposure limits and protective standards. The act authorizes OSHA to promulgate specific requirements for risk assessment, medical management, and other aspects of chemical safety at work. The Toxic Substances Control Act (TSCA) empowers EPA to regulate new and existing chemicals, and authorizes the agency to mandate development of safety data for substances that in the view of the agency may present an unreasonable risk to human health and the environment. Both statutes were enacted in response to the environmental consciousness of the 1970s, when Congress greatly expanded agency authority to intervene in the affairs of the chemical industry. Congress at the same time however also sought to circumscribe the broad delegation of powers through systematic checks on the use of administrative discretion. Both the OSHAct and TSCA are thus heavily freighted with procedural requirements and they define the obligations of federal officials much more precisely than do comparable British statutes.

British chemical safety policy is largely in the hands of the Department for Environment, Food and Rural Affairs and the Health and Safety Executive. The 1990 Environmental Protection Act contains powers to prohibit or restrict import, use or storage of substances. The 1974 Health and Safety at Work Etc. Act defines the duties of manufacturers to notify, test and, if necessary, label substances used in a workplace setting. The act enables a broad control regime implemented through statutory instruments, which in the years since 1974 has generated an extensive system of specific provisions for various industries, disciplines and risks. From 2008, earlier statutory instruments are progressively being repelled by the European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation. While British chemical control laws do endow regulatory agencies with more or less specific powers, they rarely stipulate the conditions under which government must act or the procedures it must follow. Both acts thus reflect a penchant for broad enabling legislation that confers open-ended regulatory authority on governmental departments (Vogel 1986: 177).

The chemical industry has a long and successful history in Britain. One of the most prosperous sectors of the postwar British economy, chemical companies recorded steady growth in production, stable employment, trade surpluses, and healthy profit margins. This unusual success won industry many friends in Whitehall and relations between governmental departments and the chemical industry have traditionally been intimate. In the past, the UK Chemical Industries Association (CIA) occupied a central position in the British chemicals sector. Representatives from leading companies and the CIA maintained strong ties with officials at the Department of Trade and Industry, the HSE, and the Department of the Environment (Brickman, Jasanoff and Ilgen 1985: 226f.). Although never quite as influential and powerful as the German Chemical Industry Association, VCI, the CIA nonetheless exhibited similar features,

acting as the peak organization for the British chemical and allied industries. Many smaller sectoral associations representing chemical users and specialty producers originated or were in some way affiliated to it. Over the past three decades, interest representation in the British chemical sector has however given way to greater fragmentation, with several smaller associations now vying for influence. While the CIA remains important, not least because it is the only group trying to cover the entire sector (Grote and Schneider 2006: 132f.), it has nonetheless largely fallen to other, younger organizations, such as the Nanotechnology Industries Association, to represent the interests of UK nanobusinesses.

Reflecting the economic diversity of the American chemical industry, the associational landscape in the U.S. chemical sector is vastly more complex and divided. Large numbers of specialized, partly overlapping trade associations compete for influence in Washington and in the state capitals, with little in way of an overall structure for concerted action. Owing to the competitive context, the U.S. chemical industry has tended to behave less consistently and predictably than its European counterparts: major regulatory issues have time and again found industry acting essentially as a multitude of competing and uncoordinated companies. Under these circumstances, the best industry can achieve is frequently loose, temporary alliances, plagued by internal friction (Badaracco 1985). Smaller companies, in effect represented by the Society of Chemical Manufacturers and Affiliates (SOCMA), have been among the most ardent critics of governmental intervention in the affairs of the chemical industry. The American Chemistry Council (ACC), the largest U.S. chemical trade association, has seen a steady increase in influence, since the regulatory debates of the 1970s. As the representative of many firms with varying interests and styles, ACC has however often been unable to find a position that represents its membership as a whole. At these times, individual firms have preferred to plead their own case in Washington. While both ACC and SOCMA have established affiliates to represent the nanotechnology interests of their members, independent trade associations, such as the NanoBusiness Alliance has also sprung up, adding to the cacophony of voices claiming to speak for the interests of American nanobusinesses.

PLAYING THE DELAY GAME: BUSINESS STRATEGIES IN AMERICA

The political strategies of American businesses grow from the realities of a complex decision-making environment. Congress, the president, the executive agencies, and the courts all have separate and distinct roles in relation to chemical control policy. While U.S. chemical safety laws confer broad powers of intervention on the executive agencies, systematic checks imposed by

Congress significantly constrain their *de facto* authority. Relations between Congress and the administrative agencies, not complacent in the best of circumstances, are exceptionally demanding and competitive in matters of chemical control (Brickman, Jasanoff and Ilgen 1985). These tensions are reflected in frequent and often disruptive use of congressional oversight and reauthorization powers. Congress routinely interferes in administrative decision-making either by withholding funds or by issuing reports that tell agencies precisely what to do. Although these reports are not legally binding, an agency jeopardizes its relations with Congress if their instructions are ignored. Powerful members of Congress in consequence can and do wield considerable influence over regulatory outcomes.

Apart from the watchful eye of Congress, regulators must contend with an extremely active judiciary. Liberal standing rules, coupled with elaborate legal definitions of agency responsibilities, have generated a multitude of lawsuits that keep American administrators continually on the defensive. As a result, the courts enjoy an unparalleled opportunity to second-guess administrative decisions. Taking their cue from Congress, the courts have adopted an adversarial posture towards the executive agencies. Judicial scrutiny has time and again forced administrators to revise their plans, regulations, practices and decisions (Kagan 2007: 102f.). Since statutory mandates finally are sufficiently flexible to permit systematic downgrading of considerations seen as extraneous to agency goals, it has fallen to the White House to guarantee consistency across the executive branch. Centralized review of agency actions by the Executive Office of the President reflects a long-standing preoccupation with regaining control over the regulatory process to ensure that the executive bureaucracy follow presidential policies and priorities (Percival 1991; Steinzor 2012). Mandatory economic analysis, performed under the critical supervision of the Office of Management and Budget (OMB), adds another layer of procedure to the rule-making process and fosters competitive relations within the executive branch.

The dispersion of power in the American regulatory system breeds robust competition within and between each branch of government and their overlapping jurisdictions undercut the authority of each. As Stephen Krasner (1978: 20) notes: "In the American political system negative power prevails: one actor can block the initiatives of another but cannot carry through its own preferences." While responsibility for nanomaterials thus has fallen squarely within the statutory ambit of the executive agencies, attention has not been confined to the domain of administrative decision-making. In the decade since the inception of the NNI, both House and Senate committees have convened various hearings on the human health and environmental implications of nanotechnologies. Both the coordination and funding activities of the NNI agencies have been targeted for congressional scrutiny, with the Government Accountability

Office – an independent investigative arm of Congress – launching reviews to assess EPA's efforts to understand and regulate the risks of nanomaterials (GAO 2008; 2010; 2012).

Separation of powers in turn provides organized interests with multiple points of access. Groups unable to work out an accommodation with a particular department or agency have numerous other political mechanisms at their disposal: they can turn to Congress, the courts, or the White House (Vogel 1986: 279). Since access is easily available at all levels, private interests distribute their attention correspondingly. Tailoring their actions to the adversarial format of rule-making, they maintain a combative and competitive stance against each other as well as against public officials. Gaining and maintaining influence in the open, complex and adversarial American system thus place fundamentally different demands on U.S. companies than their UK competitors. Because administrative decisions and policies can be challenged, revised or overturned at other stages of the regulatory process, companies face few incentives to seek collaborative settlements with the agencies responsible for regulating their conduct. Even if manufacturers could work out an accommodation on say nano-silver regulation, other groups can obstruct its implementation by appealing to Congress or filling court challenges. Environmental groups indeed appear increasingly bent on pursuing such strategies: both FDA and EPA have been dragged before federal courts to compel speedier and more stringent statutory action on nanomaterials. The complexities of the American decision-making environment hence give companies little reason to believe that administrators will be able to uphold their end of a cooperative arrangement. Fragmentation of regulatory powers, combined with the open decision-making process, in short renders administrative commitments ambiguous.

But the permeability of the American regulatory system cuts both ways. Just as their adversaries, American companies use the multiple channels of access to influence the direction of regulatory policy. The upshot of a policy process structured to facilitate broad participation in the formulation, implementation, and litigation of policy is that companies rarely need to look to the executive agencies to see their interests satisfied. Recourse to Congress, the courts and the White House affords companies alternative routes of influence – opportunities, which often translates into a *de facto* veto over regulatory action. Dispersion of political authority therefore detracts from the value of maintaining relationships with regulators on congenial terms. One observer concluded: "It is too easy to bring court suits and legal case against the government, against industry, against anybody, and that is not a way to maintain a good relationship."[1] The knowledge

[1] Phone interview, April 3, 2012.

that persistent challenge and loud protest can make a difference instead encourages companies to embrace a strategy of active resistance in regulatory affairs. A less aggressive posture would permit competing interests to seize the initiative and make unfavorable swings in policy more likely (Brickman, Jasanoff and Ilgen 1985: 247). The ensuing struggle for control cast opposing interests as adversaries and put a premium on their knowledge and expertise.

The adversarial nature of business-government relations in the American context has long intrigued political observers. Agency-industry relations on issues of human health and environmental safety are variously described as conflict-ridden or acrimonious, if not outright hostile. An observer remarked: "The culture in the United States is a longstanding one of antagonism between the industry and the government at least on these kinds of issues [and this] antagonistic, legalistic and combative relationship […] is an impediment to constructive cooperation."[2] 'Political culture', 'ideology' or 'American exceptionalism' may in part be to blame; but neither presents us with persuasive answers to why American companies have been reluctant to embrace the strategies of their UK competitors. The Federal Government's invitation for dialogue and cooperation did present companies with opportunities to directly influence regulatory decision-making and shape federal research priorities to suit their commercial needs; yet, while presented with ostensibly similar prospects of shaping regulatory policies, American companies have displayed manifest discomfort in cooperating with the federal regulators. Rather than revert to stereotypes concerning American business ideology, we must instead consider how decisions to disclose, bias or withhold information may advance or impair the interests of U.S. companies.

Fragmentation of authority and the adversarial system of regulation is as David Vogel (1986: 286) notes the political analogue to the highly competitive relationships that exists within the American business community. For U.S. companies, survival in the marketplace therefore not only depend on their ability to protect proprietary information from the prying eyes of competitors; equally, if not more important, is the need to limit information about their operations in the course of regulatory proceedings. The dispersion of regulatory powers encourages and rewards a series of tactics designed to protract, deflect and obstruct regulatory action. Because the proficiency of these 'delay' tactics ultimately depends on the careful management of information, nondisclosure remains a prudent business response. Cooperation with regulatory authorities is in contrast a risky gambit – not only given the ambiguity of

[2] Phone interview, April 3, 2012.

bureaucratic commitments, but because it can be construed as tacit admission of the validity of opposing views (Badaracco 1985: 129) and in many cases will make regulation more likely. Explaining the course of nondisclosure observed in chapter three in short invites a look at how the diffusion of regulatory powers in the American political system allows companies to guide the direction of regulatory policy by withholding or biasing information; and importantly how information disclosure undermines the ability to minimize regulatory interference.

The fragmentation of political authority leaves U.S. administrators in a peculiarly vulnerable position. Elected politicians and judges each guard their institutional prerogatives with caution and even jealousy (Carpenter 2001: 17). Statutory mandates must be implemented under the critical eye of other governmental institutions, and in full view of warring private interests, each advancing interpretations of law, science and economics consistent with their narrow objectives. While in principle endowed with broad powers of intervention, the *de facto* authority and autonomy of regulators is minimal. Congress is a fickle mistress, quick to defund and even quicker to blame the bureaucracy when a lack of resources undermines its capacity to prevent regulatory failures. The ambiguous delegation of power in U.S. chemical control legislation reflects a long-standing congressional preference for constraining administrative discretion through complex rule-making procedures, economic analysis requirements, implementation deadlines, and expanded judicial review. U.S. toxic substance laws in effect place the entire burden of data collection and risk assessment on agencies without the budgetary means to carry out their mandates. Although not technically required to engage in active information production and research, in reality neither OSHA nor EPA can intervene against suspect products and practices in the absence of such information. In consequence, companies, "who want to minimize regulatory intervention have little incentive to produce information showing that their products or activities are safe. Instead, they are best advised to maintain a status quo of ignorance." (Wagner 2004: 1680f.)

While TSCA for example directs EPA to regulate new and existing chemicals, no substance needs to be tested unless there is some evidence that it presents a potential risk; yet, this provision creates a 'Catch 22' for the agency:

> "Before the EPA can ask the producer to provide data to help in risk assessment of a chemical, the agency needs to show that the chemical presents an unreasonable risk to human health or the environment. EPA thus needs toxicity and exposure data that producers are not obligated to provide unless the EPA can first show that a risk exists!" (Choi, Ramachandran and Kandlikar 2009: 3030)

Although the 'unreasonable risk' standard adopted under TSCA and other federal statutes does not demand definitive proof of harm, it does require that an agency has some evidence that a substance presents a risk before it can impose testing requirements, warnings or use restrictions.

Manufacturers have time and again employed this loophole to challenge any new test requirements by arguing that EPA has insufficient evidence to demonstrate a risk of harm sufficient to justify testing (Applegate 1991). As a result, twenty two years after TSCA was enacted, EPA had tested only 263 high-priority chemicals for some specific effect, or 0.4 percent of the approximately 70,000 in commercial use in 1979 (Collins 2010: 117). While EPA spends millions of dollars each year on research related to toxic chemicals, its testing program for specific substances is relatively small. The agency instead relies heavily on information voluntarily submitted by industry when drafting proposed regulations. Because any adverse information in turn can be employed to justify stricter standards, volunteering existing data or undertaking joint safety research to enable risk management methods constitutes a risky proposition. Companies, of course, can avoid this entire scenario simply by "minimizing the amount or credibility of any existing information which indicates toxicity." (Lyndon 1989: 1820)

Elaborate statutory requirements and congressional oversight on the other hand leave little administrative discretion for deciding the course of enforcement. TSCA for instance mandates that EPA screen all chemical substances to ensure that they present no human health and environmental hazards. Where evidence of risk exists, EPA has little room to waiver a regulatory response. Companies disclosing information about their operations are therefore more likely to be greeted with fines and increased restrictions than with regulatory rewards and letters of commendation (Wagner 2004: 1625). With such irresistible reasons to resist producing information, it is no surprise that companies not only tend to shy away from cooperation, but actively seek legal protections in exchange for disclosing information, hence industry's – unsuccessful – push for incorporation of liability waivers under the NMSP. Most federal statutes thus forcefully discourage actions, which could facilitate regulators' access to information relevant to hazard or exposure assessment. An EPA official elaborated:

> "industry has a lot of data laying around, showing that certain chemicals don't have any effects. Now, they are not required by law to submit that to us and then go on their merry way. But they are not submitting that to us. […] You would think that if you were an industry and you had data that said this chemical is okay you would make sure the whole damn world knew. But that is not happening. So if they are not sharing good information… what [else] are they not sharing?"[3]

Critics maintain that U.S. toxic substances laws perpetuate perverse incentives for companies to stay ignorant of the adverse effects of their products and activities (Lyndon 1989; Wagner 2004);

[3] Interview, Washington, D.C., April 19, 2012.

industry, in any case, faces high stakes in controlling adverse information and to release it only slowly (Rudd 2008: 235).

The considerations commanding corporate dealings with the agencies are further buttressed by judicial doctrines. In remanding OSHA's benzene standard,[4] the U.S. Supreme Court inadvertently created incentives for companies to employ information as an offensive weapon. Searching review has forced administrators towards greater formality and rigor in building the evidence to support their decisions. Every comment that raises a credible-sounding issue – even a peripheral one – must receive a complete and detailed response. Submitting volumes of highly specific, very detailed, extensively documented comments on every conceivable point of contention, backed by the threat of litigation, permit companies to bury 'incriminating' information in a mountain of 'irrelevant' material with the effect of slowing down the rule-making process to a virtual standstill (Sass and Rosenberg 2011). A continuous barrage of letters, meetings, follow-up memoranda, formal and post-rule comments, petitions for reconsideration, and notices of appeal over the life cycle of a rule-making can wear down an already overstretched agency. It is thus not uncommon for the rule-making record of a single control standard to run into hundreds of pages of dense technical discussions. Overloading the rule-making process rests on the ability to make only 'carefully selected facts' available, withholding others, and if delay is useful flooding an agency with more information than it can absorb (Wagner 2010: 1400) – neither of which is conducive to candid discussions about potential sources of and solutions to hazards and exposure, which might assist agency officials filter through scores of irrelevant material.

Information excess then can be a conscious strategy deployed to exhaust federal agencies, browbeating them into capitulating on their demands by reinforcing each technical complaint and criticism with a threat of litigation (Wagner 2010: 1339). Judicial challenge of agency decisions in turn offers generous opportunities to sway the tide of regulatory action as illustrated by EPA's botched attempt to ban asbestos. A known carcinogen, 60 countries worldwide have banned the use of asbestos. Each year, ten thousand people die from asbestos-related diseases in the United States alone – a rate approaching 30 deaths per day. In 1989, after ten years of meticulous

[4] In 1980, the Supreme Court invalidated OSHA's updated standard regulating benzene, a carcinogenic component of petroleum, on the grounds that OSHA had failed to make quantitative estimates of the benefits of the standard and weigh them against the costs to see if the balance was 'unreasonable'. The *Benzene* decision created ambiguity as to how extensive OSHA needs to be in its risk analyses, forcing the agency to adopt a very cautious approach in developing its rules. Fear of rebuttal has since compelled other federal agencies to provide increasingly detailed technical explanations for their standard-setting decisions to avoid the outcome reached in *Benzene*.

research, public meetings and regulatory impact analyses, EPA issued a final rule to prohibit the future manufacture, import, processing and distribution of asbestos in almost all products. The asbestos industry responded promptly by filling suit against EPA, arguing that the rule was not promulgated on the basis of unreasonable risks. In October 1991, the U.S. Court of Appeals for the Fifth Circuit found in favor of the claimants, concluding that EPA had failed to muster substantial evidence to justify its asbestos ban (Collins 2010: 118f.).[5]

Despite overwhelming evidence that it is deadly, EPA has never succeeded in promulgating a ban on asbestos. Nor has EPA prohibited a single substance under TSCA since. But how is a substance, which globally has caused the premature deaths of thousands, if not millions, relevant to nanomaterials, which have yet – decisively – to be linked to a single health incident? Asbestos is in many ways the perfect illustration of the stakes for U.S. companies. EPA's inability to amass the scientific evidence to effectuate a ban on asbestos demonstrates the potency of court challenges as a tactic to obstruct regulatory intervention. What the asbestos and other industries learned from this experience was that mounting a successful court challenge hinges upon the ability to discredit and contest the scientific results underlying agencies' rule-making. Corporate lawyers have since become adept at employing litigation tactics designed to refute, contest and ultimately thwart regulatory action. A proficient trial lawyer will proceed from denying that a product or substance is harmful over insisting that expose is either negligible or those extrapolations from laboratory settings are unrealistic to blame avoidance citing improper use or ignorance.

Since the only reliable source of information on exposure and possible harms is often the very same companies, which stand to benefit from a successful challenge, lifting the burden of proof presents a herculean task for under-staffed and under-resourced agencies. Volunteering information to regulators may in contrast be tantamount to providing the leverage needed to justify greater regulatory interference. Consider the implications of a joint safety study: while collaborative research could help legitimize claims of safety, government inputs or funding will be accompanied by demands for influence on the design and conduct of the study as well as how it is reported. Corporate sponsors could therefore wind up in the unfortunate situation of funding a study that is not in their best interests. Companies inclined to underwrite a joint study would find it difficult to dispute, let alone suppress, 'troublesome' results in a court setting.

[5] In its ruling, the court concluded that EPA did not present sufficient evidence to justify the ban on asbestos. Specifically, the court found that because EPA had not considered all necessary evidence, the agency had failed to show that the control action it chose was the least burdensome regulation required to adequately protect human health or the environment (GAO 2005: 28f.).

Should those results form the basis for a subsequent rule-making, corporate sponsors would in effect have renounced one of their most potent means of influencing regulatory outcomes (Monica and Monica 2009: 401). While no challenge has been filled to date, corporate lawyers have indeed been sharpening their litigation defenses. In response to the highly publicized 'Poland study' (Poland *et al.* 2008), purporting to demonstrate health concerns for carbon nanotubes, trail lawyers have for example criticized the findings based on issues ranging from reliability, design and execution over underlying assumptions to the specific strain of mice employed in the study (Monica and Monica 2008). In this context, it is not difficult to imagine the likely response should EPA or OSHA decide to take strict action on CNTs.

Centralized White House review finally creates opportunities for industry to protract and obstruct agency rule-making through the backdoor. The Office of Management and Budget oversees the regulatory activities of all federal agencies to ensure that presidential policies are followed and that economic analysis is undertaken to inform regulatory policy. The heart of the presidential review program, as administered by OMB's Office of Information and Regulatory Affairs (OIRA), is the power to return a draft rule to an agency for further consideration. Because agencies must refrain from publishing rules until they have cleared White House review, OIRA can *de facto* block any regulation it finds objectionable for an indefinite period of time (Olson 1984; Steinzor, Patoka and Goodwin 2011). While relatively unknown, OIRA serves as an extraordinarily powerful gatekeeper for regulatory proposals to enter the outside world (GAO 2003; Steinzor 2012). EPA's rule-making record in the wake of the NMSP disappointment illustrates.

Skeptical of further voluntary initiatives, EPA began to look for ways of using its existing authority under TSCA. On 22 November 2010, EPA submitted a proposed Section 8(a) reporting rule for OMB review. OIRA is required to complete its review within 90 days of an agency submitting a draft regulation. This period can be extended by 30 days *once*, for a total of 120 days. At the time of writing – some 900 days later – EPA's proposed rule is still awaiting OMB approval.[6] An EPA official explained:

> "There is definitely a political football here. […] Currently, the way our government is operating, there is a big enough group in government that doesn't want to see those rules out. The Office of Management and Budget has to consider everybody's comments. They are not just going do whatever EPA wants. So there are enough people who are saying there is a problem with these rules. It could just be OMB itself is saying 'no, we don't want to do that'. Now here is the politics part of it: the way the process is supposed to work

[6] www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2070-AJ54 [Accessed July 9, 2013]

> is that OMB is supposed to review them for a certain amount of time and say 'yes' or 'no'. Well, OMB won't say no, we will not withdraw the rules, so I don't know where you go from there, when you have that stalemate. This Office of Management and Budget does not seem willing to say no to rules and I think that is because they may have somebody in their office but also people in the White House with different views."[7]

An observer added: "[The rule] is being held up because the chemical manufacturers, whose products would be subject to review by that, are holding it up – because they don't like it."[8] The proposed rule would require manufacturers to notify EPA of intended uses, production volumes, and methods of manufacture and processing as well as available exposure, release and toxicity information. According to EPA, reporting of these activities would provide needed information to consider appropriate action under TSCA.[9] Little wonder then if manufacturers 'not inclined to voluntarily test their nanoscale materials' (EPA 2009b: 27) might find relief in seeing a mandatory requirement gummed up at the OMB.

In its 30 years of existence, OIRA has earned a reputation as a business-friendly forum – a court of last resort for companies that fail to convince agency experts to weaken pending regulations (Livermore and Revesz 2013: 156-161; Bagley and Revesz 2006: 1265). Correct or not, economic analysis as practiced by OIRA does hold certain promises for industries looking to minimize regulatory interference. Because OIRA is tasked with ensuring that the benefits of regulations justify their costs, the information most likely to influence OIRA decision-makers would address the estimated costs and benefits of regulation, preferably in economic terms. Bracketing the inherent difficulties involved in monetizing the social value of a cleaner environment, much of the information needed to quantify costs lies exclusively within the particular knowledge of industry. Since the only reliable source of data needed to prepare cost estimates is often the very same companies, which stand to benefit from delay or inaction, they consequently face strong incentives to inflate such estimates. Critics maintain that within the formal cost-benefit framework, numbers that are biased, speculative, or even arbitrary are preferable to no numbers at all (Driesen 2006; Steinzor, Patoka and Goodwin 2011: 62).

Influence in the OMB process then not only depends on the ability to alert OIRA – and indirectly the White House – to the political stakes involved; equally valuable is the leverage afforded over OIRA decision-making purchased by supplying inflated estimates of technology costs and market effects. This setup again strongly discourages companies from volunteering

7 Interview, Washington, D.C., April 19, 2012.
8 Interview, Washington, D.C., April 17, 2012.
9 www.reginfo.gov/public/do/eAgendaViewRule?pubId=201010&RIN=2070-AJ54 [Accessed April 12, 2013]

information to regulatory authorities: disclosure would serve nothing but undermine industry's informational advantage and allow other groups to dispute inflated cost estimates by facilitating access to 'inside information' about an industry's operating costs. Worse still, volunteering information would assist regulators defend their rules and resists OMB arm-twisting (Olson 1984; Wagner 2004). Just as in their direct dealings with the agencies, withholding and biasing information in the OMB procedure thus present temptations which cannot easily be set aside.

Whether working through backchannels at the OMB, lobbying members of Congress, testifying at hearings or aggressively pursuing court challenges, American companies in short rarely see their interests served by volunteering information to regulatory authorities. On the contrary, companies disclosing information about products or activities seldom find their good faith rewarded. Fragmentation of political authority and the open policy process imply that companies trust administrative commitments to the detriment of their interests. Reflecting on the issue of testing, an observer noted:

> "[Companies] don't know how the public or EPA is going to respond, if they test their materials. They don't know if this test or that test is going to be considered valid. […] It could cost somewhere between a couple of million and up to ten million dollars to run a chemical all the way through the tests […] and if EPA is going to say: 'No, we haven't decided whether they will work for nanomaterials or not', then it only hurts you if no one else has to do it."[10]

The other side of the coin is of course that American companies do not need the federal agencies to realize their interest. Recourse to Congress, the courts and the White House affords companies generous alternative routes of influence – and rewards a series of tactics designed to protract, deflect and obstruct regulatory action: these include submitting volumes of data or public comments to challenge or discredit studies showing evidence of harm; using Congress to delay agency assessments via letters or budget riders; or clogging up the OMB review process through inflated cost estimates (Sass and Rosenberg 2011). The delay which can be purchased by litigation alone is often sufficient to undertake measures to reduce or eliminate the costs of an eventual adverse decision. While nondisclosure does not guarantee inaction, uncertainty and a lack of knowledge certainly act to delay a regulatory response. The very length of the regulatory debate favors industry, endowed as it is with superior organization and resources. Success in the open and adversarial American setting thus requires the marshalling of scientific and economic evidence and constant vigilance from one end of the policy process to the other. The adversarial format of regulatory proceedings demands that companies present their views as strongly as

[10] Interview, Washington, D.C., April 17, 2012.

possible, if necessary with the scientific evidence to buttress their views. A less aggressive stance – whether during lawsuits, congressional or administrative hearings – could be construed as tacit admission of the validity of opposing views and hence increase the risk of regulatory interferences. Given the ambiguity of bureaucratic commitments and because the efficacy of their delay tactics depends on the careful management of information, nondisclosure remains a sensible business response.

Strongly compelled to resist disclosure, U.S. companies have as we saw in chapter three nonetheless in isolated instances chosen to cooperate with federal agencies, *e.g.* through the NIOSH voluntary program or the NanoRelease project. Corporate decision-makers are unlikely to mistake their interests. So how can we account for these examples of government-industry collaboration? Again, exploring the risk-benefit calculations of participating companies yields a plausible explanation: in all instances, cooperation involved undeniable benefits for participants; crucially, however, cooperation entailed only marginal regulatory liabilities. Interest in collaborating with NIOSH can thus in part be attributed to the tangible benefits provided to industrial partners. Data collected by the field team was used to inform NIOSH's occupational health and safety guidance documents (NIOSH 2005; 2009), thus allowing companies to learn from the practices of their competitors. An observer explained: "the courts and the states have tended to adopt the NIOSH standards, so that they become in effect regulatory. They become binding. So to the extent that there is regulation of occupational safety and health issues in general and nano in particular it is coming from NIOSH, not from OSHA."[11] Partnering with NIOSH in short presented opportunities for industry to shape the future worker protection regime. The interest in the voluntary program thus demonstrates that U.S. companies like their UK competitors readily seek direct influence, even if it entails cooperating with federal agencies.

Here recognizing NIOSH's statutory mandate is important. NIOSH is as define by the OSHAct, OSHA's principle source of expertise. As NIOSH learns about industry practices, should companies not fear that OSHA would respond with new occupational health and safety standards? Hardly! A series of court rulings and congressional interventions have forced OSHA into a state of near-paralysis (Michaels 2008): since 2001, OSHA has issued only four new rules – all narrow in scope and uncontroversial to industry – and the agency has regulated only two chemicals since 1997 (Feldman 2011). NIOSH's institutional separation from OSHA[12] has in the

[11] Phone interview, April 3, 2012.

[12] Congress established OSHA under the U.S. Department of Labor. NIOSH is in contrast part of the Center for Disease Control and Prevention within the U.S. Department of Health and Human Services.

past proven to be a significant impediment to funneling the agency's recommendations into the regulatory process (Jasanoff 1990: 34f.). The two agencies tend in effect to pursue their objectives independently, and coordinated research programs have been few. OSHA, moreover, has acted on relatively few of the recommendations issued by NIOSH, and in several cases, where OSHA did take action, the proposed or promulgated standard varied from the NIOSH recommendation, often in the direction of greater leniency (Brickman, Jasanoff and Ilgen 1985: 159).[13] Whatever NIOSH might learn from cooperation, regulation is in other words unlikely to follow. Contrast this with the implications of volunteering information under the NMSP: with EPA unable or reluctant to guarantee liability waivers, information submitted under the scheme could trigger penalties ranging from a slap on the wrist to onerous new restrictions. No wonder then if companies felt uncomfortable volunteering information to the agency.

The NanoRelease project on the other hand illustrates that U.S. manufacturers are in fact ready to cooperate with regulators, including EPA. Again, however, industry would appear to incur only marginal risks of interference. The NanoRelease project is not primarily designed for regulatory purposes, but aims to develop the scientific tools necessary to support decision-making among NGOs, businesses, and governments. Unlike the British PROSPEcT project, which intends to provide a full characterization of the analyzed materials, NanoRelease considers only release and exposure scenarios. Insights to such questions may prove valuable for developing quality exposure and risk assessments. But as ILSI emphasizes, "[d]ata generated from this project alone is not sufficient to characterize exposures and thus, would not be sufficient to assess risk or determine regulatory outcomes."[14] These are not merely empty gestures to encourage manufacturers to submit their materials for testing.

Participating companies are expected to submit candidate test materials to a third-party coordinator for repackaging and labeling with random sample numbers. Repackaged samples are sent to testing laboratories for blind analyses. All results are reported to the steering committee by sample numbers only – neither laboratory nor steering committee members will know which sample numbers correspond to which company (Roberts 2011). The implications are subtle, but profound: neither EPA nor other federal agencies will have access to the 'raw' data from the NanoRelease project. Although NanoRelease will assist the agencies in developing needed risk

[13] NIOSH has for example identified 682 toxic chemicals to which workers are exposed. OSHA has no existing regulations for 244 of these chemicals – workers can be exposed to them at any level. For another 196 chemicals, OSHA's standards offer less protection than NIOSH's recommendation. In some cases, OSHA rules allow for exposure at levels that are hundreds of times higher than NIOSH guidelines (Feldman 2011: 9).

[14] www.ilsi.org/ResearchFoundation/RSIA/Pages/NanoReleaseFAQs.aspx [Accessed April 9, 2013]

management methodologies, the aggregate results alone will be insufficient to justify stricter regulations to curb exposure to carbon nanotubes or other nanoscale materials. Only the raw data would suffice to lift the burden of demonstrating unreasonable risk. Even if evidence of potential harms for CNTs are established in the future, the range of release scenarios documented by the NanoRelease project and the anonymity guaranteed by the steering committee will in short leave ample room for manufacturers to deny specific exposure to their products. And, regardless of what the project may find, questions of how evidence of harm should be interpreted and extrapolated remain of course free game for trial lawyers.

PERSUADING WHITEHALL: BUSINESS STRATEGIES IN BRITAIN

Few, if any, of the delay tactics employed by American industry are available to UK companies. Where opportunities for obstruction exist, they are best avoided by companies seeking to sway the direction of British chemical control policy. Deference to administrative decisions is instead a sound strategy under a political regime which vests authority firmly in the hands of the executive. The combination of parliamentary sovereignty and a first-past-the-post electoral system endows Britain with enormously powerful single-party governments. Once elected, British governments face few significant constitutional or political checks on their legislative powers (Wood 2001). Unlike Congress, Parliament enjoys neither the independent expertise nor the separate political base needed to compete with the executive. The bonds of party affiliation significantly reduce the autonomy of the Commons, while the powers of the House of Lords have whittled away by successive acts of Parliament. Oversight through special investigations addresses only the broadest policy issues, with the parliamentary question representing virtually the only device for calling ministers to account on more specific administrative decisions. Cooperation between the two policy-making branches is thus the rule in British politics. Parliamentary sovereignty affords the judiciary only limited powers to review statutes passed by Parliament. Suits against governmental agencies by private parties are extremely rare, even where regulatory policies seriously impinge on their economic interests. Cabinet government finally eliminates most of the competitive dynamics characteristic of the American executive. Institutionalized inter-ministerial consultation and negotiation reinforces the authoritative character of chemicals regulation by placing the government as a whole behind decisions to intervene.

The legal and institutional factors, which predispose the Federal Government to internal competition, are thus largely absent in Britain. Centralization of regulatory powers in Whitehall allows the executive to exercise unquestioned leadership in the formulation and implementation

of chemical control policy. Contrast for example legislative interests in nanotechnologies in Britain with the United States: Congress has as we saw above taken a keen interest in federal activities related to the human health and environmental implications of nanotechnologies. No similar display of interest is evident in Britain. Parliamentary questions in the Commons have been confined to broad inquiries concerning funding for nanoscience and technology, with little or no concern expressed for potential adverse effects and much less for governmental efforts to address them. In 2010, the House of Lords Science and Technology Committee launched an inquiry into the use of nanotechnologies in the food sector. Highly critical of the food industry for failing to be transparent about the uses of nanomaterials, the Committee however took no issue with governmental policies. Rather, the Committee commended HM Government's commitment to enable appropriate controls, with recommendations limited to calls for government to ensure adequate research funding (House of Lords 2010a; 2010b).

Neither legislative scrutiny nor reviews by independent non-departmental bodies such as the Council for Science and Technology (2007) or the Royal Commission on Environmental Pollution (2008) have thus given HM Government cause to reconsider its regulatory priorities or strategies (HM Government 2008; 2009; 2010). Because the executive controls the process of drafting legislation, statutory objectives conform rather closely to the government's regulatory agenda. Parliament ratifies the broad outlines of policy in enabling legislation, committing the details of implementation to the discretion of the executive. Representatives of economic and social actors consequently enjoy fewer avenues for directly influencing policy outcomes (Rose 2004: 189f.); and UK companies therefore confronts a very different decision-making environment than their U.S. competitors. Steward Wood (2001: 259) observes, "the legislative strength of British governments brings uncertainty to the political economy […]. Because governments have the capacity to introduce radical changes of policy at will […] companies face overwhelming incentives to withhold rather than share information […]." Yet, this presents us with conundrum. If governmental commitments are of a questionable nature, how can we account for the story of nanotech regulation in the United Kingdom, fraught as it is with examples of collaborative engagements and extensive information sharing among governmental entities, companies and their representatives?

Doubts concerning a commitment to uphold a collaborative agreement would certainly merit caution. Policy preferences change over time; and if left unchecked, the use of the state's discretionary powers could inflict significant harm on business. In democratic politics, short-term shifts in government policy are more often than not driven by concerns for the prospect of (re-)election. Neither chemical safety however – nor nanotechnologies for that matter – is of a

nature to make or break the electoral fortunes of governments. Unlike economic or labor market policy, questions of chemical safety, by virtue of their technical obscurity, rarely lend weight to partisan contestation. Except for a few instances, where specific regulatory issues have achieve a high political profile, chemical control policy in Britain remains a matter of executive discretion.

Just as Parliament is content to confer open-ended regulatory authority on ministers, so successive governments have preferred to entrust virtually all important decisions to civil servants. Although the legislative strength of British governments thus may bring uncertainty to the political economy, delegation of regulatory powers to administrative authorities exercises a significant stabilizing influence on the direction of chemical control policy. Insulated from the political process, state bureaucrats face different incentives than elected politicians: as they are not subject to the short time horizons imposed by the electoral process, state bureaucrats can pursue their statutory objectives, even when those objectives no longer enjoy popular support. The absence of legislative-executive competition moreover eliminates the pressure for rigorous procedural and judicial controls on the bureaucracy. Since Parliament have neither the means nor the incentives to exercise effective post-legislative control, British regulators enjoy considerable independence in implementing chemical control laws. In contrast to the United States, then, the locus of regulatory authority rests with the executive bureaucracy; and this dictates a strategic orientation towards the regulatory authorities not found in the American separation of powers system.

Concentration of regulatory powers on one hand affords UK companies opportunities not enjoyed by their U.S. competitors – but it also weighs heavily on their strategic options. Industry may find some measure of protection against meddling bureaucrats in the process of inter-ministerial consultation and negotiation. In the past, the UK chemical industry could rely on the Department of Trade and Industry, which acted as its sponsoring department, to defend industry against overly zealous environmental health and safety regulations (Paterson 1991: 237; Grant, Paterson and Whitston 1988: 77ff.). Interviews with officials at the now reconstituted Department of Business, Innovation & Skills (BIS) made clear that old sympathies for industry and its main trade association, CIA, still linger in the ministry.[15] With BIS assuming the lead on UK nanotech policy in 2008, recourse to their traditional 'champion in government' might serve to place a break on regulatory action. Appealing to the ministers charged with workplace or environmental safety might likewise exercise a moderating influence. Nonetheless, with day-to-

[15] Interview, London, March 3, 2011.

day responsibility ultimately a question of administrative discretion, UK companies cannot afford to ignore much less antagonize the executive bureaucracies.

Gaining influence in the British regulatory system thus hinges upon convincing state bureaucrats by the expertise social actors bring to the table. In contrast to their American colleagues, British regulators are largely free to structure and manage access to administrative proceedings. As in the legislative process, limiting access to the administrative decision-making process enhances bureaucratic control over regulatory outcomes. Groups consciously or inadvertently excluded from consultation may find that their views fall on deaf ears. Those allowed to comment on rules, especially during their formative stages, can in contrast exercise considerable influence on their final formulation. Expertise and information is of course the most effective key to unlocking the door of consultative proceedings; but companies are not the only source of information; and they certainly do not have a monopoly on expertise. Although comparatively disadvantaged in terms of resources, other groups also offer advice on chemical hazards. State bureaucrats likewise have their own sources of information. Exclusion from administrative deliberations therefore risks the imposition of decisions that run counter to corporate interests as competing interests seize opportunities to guide the direction of chemical control policy.

Since influence is purchased through access to state authorities, companies must in other words be cautious of tactics that could be viewed as disruptive to ongoing relationships. While the tactics of American industry are well-suited to protract and impede regulatory rule-making, their first concern is not with maintaining relationships with regulators on congenial terms (Coglianese 1996). Overlapping jurisdictions and the open decision-making process in the United States mitigates this problem. But this is a luxury not afforded to UK companies. Industry stands to gain little from taking agencies to court, launching media campaigns and lobbying individual MPs – tactics which when used have often cost industries more friends than they gained (See *e.g.* Macmillan and Turner 1987). Organized interests fielding tactics viewed as disruptive or subversive have in the past found their access to regulatory proceeding impaired by barely concealed bureaucratic animosity (Grant 2004: 408f.). Disputing or obstructing bureaucratic decisions thus remains a precarious gambit, lest industry risk exchanging the blissful opacity of administrative decision-making for the noisy politics of partisan contestation or the court of public opinion (Culpepper 2011: 181ff.).

Absent recourse to the courts or Parliament – and knowing full-well that regulators at Defra and HSE had the power to decide policy – companies could tread few alternatives paths to influence the outcome of the regulatory process. Because companies have to win what they can

during administrative deliberations, volunteering information, sharing expertise and collaborating with regulators is often the sensible response; and as we have seen UK companies have indeed sought to cultivate relationships with regulators that emphasize close and informal cooperation. The limited prospects of political interference or judicial scrutiny on the other hand also helped bolster corporate confidence that administrative decisions and policies would not suffer sudden or unpredictable reversals. Since regulators in other words were largely free to carve out a regulatory response to nanotech according to their interpretations, conclusions and priorities, industry readily accepted that the commitment to pursue a set of collaborative policies was credible. The promise of influence entailed by HM Government's regulatory strategy in turn presented compelling incentives for UK companies to embark on a strategy of information disclosure with the aim of molding regulatory decisions to their strategic advantage. Through informal consultation, negotiation and collaborations, industry has left a distinct mark on the development of UK nanotech policy, and has significantly contributed to building the scientific basis available to regulators for risk assessment and management of nanomaterials. Concentration of regulatory powers in state bureaucracies has thus in short created the critical impetus for cooperation.

A quarter century ago, Ronald Brickman and colleagues (1985: 227) writing on chemical control policy concluded: "Informality is the preferred way of conducting regulatory business in Britain; a legacy of trust and good feelings has permitted the tackling of tough policy problems in a spirit of accommodation rather than confrontation." At first glance, the story of nanotech regulation in Britain would appear to share some affinity with this assessment. We should of course be wary of unquestioningly accepting an enduring 'British style of regulation'. Much can – and has changed in the span of 25 years, including the nature of business regulation. Writing in the mid-1980s, Brickman and colleagues drew on observations of a system of governance which has largely ceased to be. From the late 1980s, business in Britain faced a policy environment very different from that which had historically been dominant: one where many assumptions about the right of business to control its own affairs were now open to challenge. The broader trends underlying this transformation are familiar: the exhaustion of old modes of governing, Thatcherism, and a radical shift in the scope and style of regulation has ushered in a new division of labor between state and society (Levi-Faur 2005).

Michael Moran (2003) admirably demonstrates how these developments have been associated with the breakdown of old, enclosed regulatory communities to be replaced by what he labels a 'new' British regulatory state. Presenting evidence from a wide range of domains – from environmental regulation over the newly privatized utilities to competition policy – Moran paints

a consistent picture. Domains once regulated informally and cooperatively with business have seen a shift to more elaborately codified regulatory frameworks coupled with a greater insistence on enforcement of rules against regulated entities. The decline of the British consensual style is said to have been accompanied by a parallel increase in the formality of relations between regulators and regulated. The development of more codified frameworks for industry has been associated with a marked decline in the reliance on informal compliance and the cooperative character of relations (Wilks 1999: 347ff.). The reorganization of regulatory institutions, combined with a new tendency to formalize both substance and procedures has caused a shift towards a more adversarial system, where regulators no longer hesitate to threaten, and use, legal sanctions (Moran 2003: 131-136). The rise of the regulatory state is in short seen as a harbinger of a new, more transparent, open and adversarial system, which has unsettled the wider system of business regulation in Britain. But how should we reconcile this diagnosis with the informal and cooperative nature of relationships evident in the story of nanotech regulation in the United Kingdom?

Broader trends always risk obscuring important sectoral variations.[16] Rather than an isolated instance of cooperation or a resurgence of the patterns of old, the UK nanotech story must however be understood in the wider context of governmental strategies for chemical safety in Britain and in Europe. The demise in Britain of the institutions and culture of 'cooperative regulation' (Moran 2006: 461) has coincided with the accession of EU competences in areas of human health and environmental integrity. The increased scope and intensity of EU regulation has significantly contributed to unraveling the cohesiveness of regulatory communities and their replacement by more formally organized, codified regulatory regimes. Widely recognized as "the most sensible legislative framework for the regulation of nanomaterials" (HM Government 2009: 19), the ambitious new EU chemicals regime, REACH, might therefore be expected to herald similar transformations in the chemical control area. Such expectations are nonetheless premature.

A profoundly complex regime, at its core, REACH consists of two elements: an innovative market-based information requirement and a more traditional regulatory authorization aspect

[16] Curiously, one area, which sits uncomfortably within the new formalized and codified approach to governing depictured by Moran, is chemical safety at work (2003: 136ff.): the 1974 Health and Safety at Work Etc. Act established the Health and Safety Commission as the competent policy-making body, with the HSE acting as its executive arm. Until its merger with HSE in 2008, the Commission was formally constituted on a tripartite basis with equal representation for local governments, labor, and management. Under the current setup, HSE's advisory network retains important elements of the old tripartite system, particularly with respect to the type of interests represented on advisory bodies and the reliance on informal relations.

(European Commission 2007; Fisher 2008). REACH privatizes information collection, provision and assessment: to place substances on the European market, manufacturers, importers and users of chemicals must demonstrate that risks are adequately controlled or that their socio-economic benefits outweigh the risks. REACH in short reverses the burden of proof from regulatory authorities to industry. But although REACH marks an important watershed in EU chemicals policy, this will neither fundamentally alter nor alleviate the dynamics of chemical control policy outlined in chapter two; and its impact on the nature of regulatory decision-making in the UK chemical safety sector has been – and will likely remain – relatively minor.

While the new European chemicals regulator, ECHA, receives and evaluates registrations for their compliance, evaluation of selected substances is undertaken by national authorities. The interests and especially capabilities of national authorities will thus be paramount to the implementation of the new chemicals regime. Current projections expect that Member States will be able to evaluate four to six substances per year. As presently planned, observers therefore predict that it will take some 60 years to complete the substance evaluation process (Williams, Panko and Paustenbach 2009: 567). Far from rendering voluntary information disclosure irrelevant, their taxing responsibilities under REACH only accentuates the need for national regulators to gain access to industry data and expertise. Although REACH in short endows regulators with new authority to mandate data production and disclosure, determining whether companies have provided complete responses remains as before a challenge. A failure to make any response will be clear, but inaccurate submissions are hard to police, if regulators cannot independently verify the information (Coglianese, Zeckhauser and Parson 2004: 306f.).

Encouraging companies to volunteer information and share their expertise with regulators therefore remains an attractive strategy – a strategic priority moreover which has proven remarkably resilient to the broader dismantling of regulatory communities in Britain: the 1999 UK Chemicals Strategy, published in the lead up to the reorientation of European chemicals policy, thus acknowledged that protecting human health and environmental integrity "can only be achieved effectively through partnership between Government [and] the chemical industry […]." (DETR 1999: 10) The strategy cements past commitments to cooperation, voluntary action and dialogue, emphasizing that "[r]isk management strategies in partnership with industry will be agreed without having to wait for lengthy legislative processes." (DETR 1999: 7f.) With the aim of building trust, the strategy established new institutional venues to allow industry expertise and views to flow into the formulation of policy and priorities. Collaboration among companies and regulatory authorities in the context of nanotechnologies thus builds on and reflects a broader pattern of voluntarism, informal consultation and partnership in the UK chemical safety area.

For industry on the other hand the new European chemicals regime has not rendered domestic regulators irrelevant. Insofar national authorities exercise significant influence in the ECHA decision-making process, recourse to state bureaucrats continues to present opportunities worth cultivating. Although the locus of policy-making may have shifted towards the European Union, creating new venues and access points for organized interests, the 'national route' remains important (Mazey and Richardson 1992: 98; 2006: 263f.; Bennett 1997). Whether sensitizing national decision-makers to their views and interests prior to European negotiations or in the subsequent implementation and enforcement process, access to state bureaucrats is a singularly important, if no longer exclusive route of influence for UK companies. As decisions about the regulatory status of nanomaterials under REACH will be made in coming years, industry will in short find its capacity to influence regulatory outcomes dependent on access to national decision-makers; and, as in the past, influence will be predicated on maintaining relationships on congenial terms.

CONCLUSION

There is a postscript to the story of nanotech regulation in the United States. After several years of speculating whether, when, and how EPA might choose to regulate nanoscale materials under TSCA, the agency in fairly rapid succession undertook a number of formal regulatory actions. Reversing the agency's much criticized position on nanomaterials under TSCA,[17] EPA in late 2008 began promulgating significant new use rules (SNURs) covering carbon nanotubes and other specific nanomaterials. A SNUR affords EPA the opportunity to review the designated use of a chemical in a manner virtually identical to the way it reviews a new chemical substance: manufacturers of nanomaterials subject to a SNUR are compelled to notify EPA at least 90 days before they begin production. Pre-manufacture notice permits EPA to evaluate the intended use of a substance and decide whether more information is needed to assess its risks or if necessary issue an order that prohibits or restricts use. There is a catch to this sudden burst of regulatory activity at EPA, however. A SNUR does not regulate a chemical's production or use. It only requires pre-manufacture notification. If EPA does not act within the 90 day period, production

[17] In January 2008, EPA published a *General Approach* for determining if a nanoscale material is a new chemical substance under TSCA (EPA 2008). Controversy over this approach arose, because EPA's insistence on molecular identity ignored physical attributes, such as *e.g.* particle size. Nanoscale versions of well-known substances, such as graphite (carbon), would consequently not be subject to TSCA provisions on notification and testing of new chemicals (Bashaw 2009: 479f.).

may commence. Any restrictions on production or use require EPA to demonstrate 'unreasonable risk' and promulgate a separate rule. EPA in other words confronts the familiar 'Catch 22' situation; *i.e.* before the agency can demonstrate 'unreasonable risk' it needs to convince producers to provide toxicity and exposure data that they are not obliged to provide unless there is some evidence of a potential risk (Wagner 2004: 1671). As before, then, companies face overwhelming incentives to withhold rather than share information – SNURs and pre-manufacture notice do little to alter this picture.[18]

An industry insider concluded: "EPA is now reviewing any nanoscale material [and] there is a public perception of EPA review and approval and now a more predictable business response. [This] gives industry some comfort that there is a predictable regulatory response, so it is not nearly as intimidating as it used to be."[19] The insider continued:

> "There has been a lack of widespread understanding of what [impact] these TSCA rules or any rule would have on the commercialization of nanotechnology. […] Some people think 'no regulation is appropriate', while others of us believe that if you don't have some EPA review the likelihood of getting widespread stakeholder buy-in on the safety front is much more difficult […]. To me you can't have it both ways. You can't say 'no TSCA reform and no SNURs, status quo' and expect people to buy into the safety proposition. [But] there is no appetite for [regulation] in industry right now, because less regulation is preferable. It's cheaper, but ultimately it is just not very good for the technology."[20]

Contrast the situation in the United States with UK policies on carbon nanotubes: responding to evidence that certain CNTs could produce reactions similar to asbestos fibers, Defra sought advice from the academic and industrial research community on the use of CNTs in consumer products. Defra next commissioned life cycle exposure studies with the Food and Environment Research Agency, carried out in cooperation with industrial experts. Satisfied that current applications of CNTs were unlikely to present serious risks to the public, Defra concluded that no further protective measures were needed. Drawing on inputs from its advisory network, HSE meanwhile issued first general guidance on management issues related to nanomaterials, followed in spring 2009 by specific guidance on the safe use and handling of carbon nanotubes (HSE 2009b). UK policies for bridging and managing the potential human health and environmental risks of CNTs thus illustrate a penchant for drawing in industrial expertise in deciding the proper course of action. The impact on regulatory decision-making leveraged by such information hints at the strong incentives for British companies to volunteer information to regulators.

[18] EPA for example estimates that most pre-manufacture notices do not include test data of any type, and only about 15 percent include health or safety test data (GAO 2005: 11).
[19] Interview, Washington, D.C., April 16, 2012.
[20] Interview, Washington, D.C., April 16, 2012.

Table 5.1 Drivers of British and U.S. Business Responses

	BRITAIN	UNITED STATES
Regulatory Strategy	Encourage cooperation	Encourage cooperation
Regulatory Powers	State bureaucrats endowed with broad discretionary authority	State bureaucrats enjoy limited discretionary authority
	➢ The limited prospect of parliamentary interference or judicial scrutiny reduces uncertainties about the future direction of UK nanotech policy	➢ The prospect of congressional, White House or judicial interference creates uncertainty about the future direction of federal nanotech policies
	➢ Industry targets administrative authorities in an attempt to influence regulatory agendas and priorities	➢ Industry diverts efforts to influence federal nanotech policies across multiple policy-making venues
	➢ State authorities signal interest in accommodating corporate concerns in the design and implementation of UK nanotech policies	➢ Elaborate statutory requirements and congressional oversight limits the scope for accommodation of corporate interests in the design of federal nanotech policies
	➢ HM Government's regulatory strategy creates compelling incentives for UK companies to disclose sensitive information in exchange for influence over administrate decisions and policies	➢ The unpredictability of regulatory responses, coupled with generous access to other decision-making venues, creates few incentives for companies to volunteer sensitive information
Bureaucratic Commitments	Credible	Ambiguous
Business Response	Disclosure	Nondisclosure
Outcome	Joint Decisions	Governmental Inaction
Nature of Industry Influence	Direct	Indirect
Implications for Business Interests	Business predictability Best practice guidelines Stakeholder confidence	Business predictability Lack of test methods and statutory guidance documents

Neither SNURs nor HSE guidance documents imposes significant burdens or compliance costs on American or British companies. From an industry perspective each outcome may be equally agreeable. But whereas safeguarding their interests requires American companies to keep agencies guessing about the nature of their products and operations, concentration of regulatory powers in Britain dictates a strategic orientation towards the executive bureaucracy. Table 4.1 summarizes the different drivers of business responses to the regulatory process and its results

across the two countries (classified according to the 'outcomes' sketched in chapter two). Leverage over the course of UK regulatory politics is thus purchased by volunteering information and making industrial expertise available to the authorities responsible for regulating their behavior. British companies in consequence sought to cultivate close and collaborative relationships with regulatory officials. And, through informal consultation, negotiation and collaborations, industry has as we have seen left a distinct mark on the development of UK nanotech policies. Ongoing dialogue among officials and industry representatives has witnessed extensive accommodation of corporate interests and the identification of agreed research priorities, development of new risk management methodologies and the joint drafting of statutory guidance documents. Broad agreement on the future course of British nanotechnology policy has in short facilitated greater regulatory certainty and hence helped stabilize the commercial environment for UK companies.

Because the American political system in contrast diffuses and fragments political authority, companies able to navigate the multiple decision-making venues rarely need to look to federal regulators to see their interests satisfied. When information is sorely incomplete, controverted, or effectively unobtainable, the executive agencies usually find it impossible to justify strict regulatory action. And, they are in effect forced to refrain from intervening against suspect substances or, as illustrated by EPA's rule-making record, limit intervention to minor adjustments under existing statutes. But while the regulatory process thus has brought greater business predictability, it has also failed to address some of the persistent challenges in the current commercial environment. The absence of certified test methods, in combination with a lack of guidance documents on environmental safety precautions, continues to create market frictions, in particular as a result of uncertainties over the industry's long-term liability exposure – with observers now heralding the coming age of mass nanotech litigation (Delany 2006; DeVries, Gotting and Liebfarth 2010).

The regulatory process did nonetheless bring relief for an industry keen on clarifying the extent of its statutory obligations. And, with the generous opportunities to protract, obstruct and ultimately deflect regulatory intervention that result from the realities of the American political system, this may well translate into a long-term stable outcome – albeit it will as before demand the marshalling of scientific and economic evidence and constant vigilance from one end of the policy process to the other. Given industry's superior resources and informational advantages, overlapping jurisdictions thus allow companies to guide the direction of regulatory policy through indirect means. Since inaction serves their interests in minimizing regulatory burdens, American companies have in short had little reason to embark on a risky strategy of information disclosure.

With the business predictability that flows from the status quo, the benefits cannot be dismissed, although it may as predicted by the industry insider carry long-term implications for public acceptance of nanotechnologies.

CHAPTER FIVE

A Meeting of Minds: The Politics of Nanotech Regulation in Germany and Denmark

The acquiescent reactions of Danish companies to the evolving regulatory process stand in sharp contrast to the assiduous response of their German competitors. In this chapter, we explore the roots of the diverging industry responses in the two countries. The patterns of behavior observed in chapter three invite our curiosity on two counts. First, Germany and Denmark belong to the group of coordinated market economies. From a varieties of capitalism perspective, the varied reactions of German and Danish companies to comparable state policies must therefore appear as puzzling as the contrasting strategies of their Anglo-American competitors. Despite German federalism, the nature of legal and institutional relationships found in the two countries chemicals sectors are however comparable, and the different business responses thus cannot reflect variations in the prospect of political or judicial interference in regulatory proceedings.

Second, while the reactions of German companies differ markedly from their Danish competitors, their responses also compares to that of British companies. In both countries, industry adopted a strategy of close, informal cooperation with government officials. The coincidence of business responses in Britain and Germany alerts us to a perhaps more fundamental conundrum. Whether we insist that business strategies are born of the distinct organizing logic of a country's political economy, its state-society traditions or some third configuration of institutions and processes, Britain and Germany are invariably placed in different categories. Conventional wisdom in short would lead us to expect different – not similar – reactions and behaviors from industries in Britain and Germany. How can we account for the coincidence of business responses observed in these two countries? And why did German and Danish companies not react alike? To answer these questions, this chapter further probes the institutional drivers of business strategies in regulatory politics. I contend that the different responses of German and Danish companies – and the coincidence of business strategies in Germany and Britain – are rooted in the institutions that structure communications among state actors and industry representatives.

State bureaucrats are in all three countries empowered to determine what chemicals to regulate, in what order, by what means, and how stringently. Scrutiny by national parliaments or the courts has little direct bearing on administrative proceedings and regulatory outcomes. Formal institutions and their operating procedures in other words exercise a similar effect on business expectations about the future behavior of state bureaucrats. But the strategic environment for chemical control policy in Britain, Germany and Denmark nonetheless differs. No government wants to regulate a chemical unless it shows a high potential for inflicting harm on humans or the environment. But in many cases the evidence of harm is sketchy, based on studies of variable design and quality, and subject to interpretation according to changing assumptions and analytic judgments. Depending on their specific agendas, priorities and preferences, regulators may react remarkably different to evidence of harm. Unless companies understand the designs and intentions of their regulatory adversaries, they cannot predict how requested information might be put to use – and they must therefore be cautious of sharing information about their operations. Deliberative institutions I contend are in turn crucial to dispel possible misgivings in bureaucratic commitments.

In the varieties of capitalism tradition, deliberative institutions are seen as important elements of the coordinated market economy that endow actors with a capacity for strategic action when faced with new or unfamiliar challenges (Culpepper 2001: 79f.; Hall and Thelen 2009: 12f.). In regulatory politics, deliberative institutions predominantly take the format of advisory bodies that allow state bureaucrats to consult external sources of expertise and garner the views of stakeholders. Advisory committees and stakeholder panels create opportunities for participants to develop common understandings of difficult-to-resolve scientific and technical problems, craft agreed solutions and settle disagreements through discussion and negotiation. As vehicles of organized discussion among officials and representatives from industry, advisory bodies afford industry opportunities to learn how officials understand the evidence of harm and evaluate the need for new controls. Based on this knowledge, companies are better able to gauge the intentions of state bureaucrats and hence predict their probable reactions to new information. Confidence in the designs of state bureaucrats can in turn persuade companies to volunteer sensitive information. Where such expectations in contrast are not well-founded, companies must remain vigilant to possible concealed agendas. Insulated bureaucratic decision-making processes broken only by *ad hoc* consultations do not give industry representatives the same opportunities for 'a meeting of minds' and companies are therefore left without a reliable basis to predict probable outcomes. Discomfort in the intentions of regulators and the unpredictability of their responses consequently hampers incentives to volunteer information.

The chapter proceeds in six steps: a first section introduces the German and Danish chemical control regimes. Sections two, three and four connect the different industry responses to the institutions that structure communications among regulators and companies. I demonstrate how the extensive reliance on advisory bodies in the German chemical safety sector buttress the credibility of bureaucratic commitments; and how confidence in the intentions of federal authorities have created compelling incentives for companies to share their information, expertise and experiences. I further show how uncertainty about the designs of state bureaucrats in Denmark inhibits incentives to volunteer information. A fifth section revisits the American and British nanotech experiences to consider potential overlaps between my account of business responses in this and the preceding chapter. I demonstrate how deliberative institutions are an important element of the UK nanotech story; and how their impact on business responses in the United States in contrast has been negligible. A final section reflects on what lessons we can draw from the analysis of nanotech regulation in America and Europe.

ORGANIZING FOR CHEMICAL SAFETY IN GERMANY AND DENMARK

In Germany, the Federal Ministry of the Environment and the Ministry of Labor and Social Affairs share responsibility for the formulation and administration of chemical control policy. The Hazardous Substances Ordinance contains powers to restrict or ban production and use of substances as well as issue specific rules for handling. The ordinance is implemented through technical rules elaborated on a tripartite basis by the Committee on Hazardous Substances. The 1980 Chemicals Act regulates a manufacturer's duties to notify, test and, if necessary, label new substances. Notifications are validated by the Federal Institute for Occupational Safety and Health and then forwarded to other federal agencies for further expert and risk assessment. While the Chemicals Act entails powers to prohibit hazardous substances, it also defines in specific detail the responsibilities of the administration and the precise notification and testing obligations of industry: substances marketed in quantities of less than 10 kilos per year are exempt from notification and long-term effects must be tested only when a substance is marketed in quantities of more than 100 tons a year. There are no provisions for testing existing chemicals. The relatively narrow scope of the Chemicals Act reflects a political compromise with industry meant to limit the act's economic impact and ensure a predictable regulatory environment.

The postwar economic recovery in Germany is intimately tied to the chemical industry. With a broad technological base, a preference for large-scale enterprise, and an excellent working

relationship with labor, the chemical industry responded to the lucrative opportunities at home and in the European common market with remarkable growth records. The German chemical industry is the dominant European chemical industry, second only to the United States and Japan. In this environment, there was little need for the state (Ilgen 1983; Grant, Paterson and Whitston 1988); and governmental intervention in the affairs of the chemical industry developed only slowly. In the debates over national environmental policy in the 1970s, the practice of formal discussion and consultation was raised to an organizing principle (*Kooperationsprinzip*) (Brickman, Jasanoff and Ilgen 1985; Schneider 1985: 182f.). Regular cooperation among specified interest groups remains today a requirement for the development of toxic substance regulations. The Verband der Chemischen Industrie (VCI) represents the interests of more than 90 percent of the enterprises operating in the German chemical sector (Grote and Schneider 2006: 129). Regional associations deal with matters of concern in the individual *Länder*, while specialized sector associations are responsible for specific groups of products or product areas (*e.g.* organic chemistry or food additives). With a near monopoly on representation, there is no significant branch or sector association outside the peak association.

In Denmark, chemical control policy is laid down in broad enabling legislation that confers open-ended regulatory authority on state authorities. Similar to Britain, chemical safety standards are implemented through statutory instruments that are routinely negotiated among authorities and affected interests (Andersen, Christiansen and Winter 1998; Christiansen, Nørgaard and Sidenius 2004). Administrative responsibility for chemical safety policy lies with the Danish Environmental Protection Agency, Miljøstyrelsen, and the Danish Working Environment Authority, Arbejdstilsynet. An employer's obligations for occupational health and safety are defined by the Working Environment Act and implemented though statutory orders prescribing more specific measures concerning the handling of substances and products. The 1979 Act on Chemical Substances and Products empowers MST to regulate new and existing chemicals. In combination with the 1973 Environmental Protection Act, the Chemicals Act enables a broad control regime covering notification, classification and labelling of substances, procedures for evaluating the risks of existing chemicals and restrictions on hazardous substances and preparations. While chemicals regulation is one of the most harmonized sectors of the EU, Denmark has in the past made extensive use of Treaty provisions enabling more stringent national regulation to ban or restrict use of specific substances (See Boye and Ege 1999).

Although moderately successful in economic terms, the Danish chemical industry boasts little of the political clout and influence of its powerful German counterpart. Whereas for example the agricultural sector time and again has demonstrated the political strength to resist or obstruct

governmental policies, the question facing chemical companies has instead been how to adapt to and if possible benefit from state intervention. The chemical sector is *de facto* split between the two main representational branches of Danish industry: the Confederation of Danish Industry, DI, organizes industrial users of chemicals, while the Danish Chamber of Commerce, Dansk Erhverv, represents the interests of commercial importers and distributers of chemicals as well as major allied branches of the chemicals industry, such as pharmaceuticals, cosmetics and detergents. Pesticide manufacturers – in effect large international chemical corporations – have meanwhile preferred to establish representative organizations independent of DI and Dansk Erhverv. Although these organizational divisions do not necessarily give rise to competition, they do preclude the industry from speaking with the weight that follows from being organized under one roof. New independent 'nanobusiness' associations have finally been created in neither Germany nor Denmark. In both countries, it has instead fallen to established associations to voice the views and interests of members commercializing nanotechnologies.

GERMANY: DELIBERATING NANOTECH

In Germany, the nanotech debate was funneled through organizational venues that promote ongoing, collective discussion among participants. Membership of these deliberative fora brings experts from industry in close and permanent contact with their academic and governmental peers, and encourages members to develop common understandings of joint problems, gather and analyze information about the consequences of different decisions and reach agreed recommendations. We encountered the most conspicuous such venue in chapter three: the German NanoKommission. Established in late 2006, the commission involved more than 100 experts and representatives from federal and Länder authorities, individual scientists, industry and civil society organizations. Acting as the steering committee for the national NanoDialogue, the NanoKommission oversaw the coordination of federal departments and their nanotech initiatives and policies. Discussions within the NanoKommission were meant to inform federal decision-makers on issues ranging from research priorities to the evaluation of scientific developments. Extensive deliberations and – at times – intense negotiations among participants generated recommendations on the implementation of preliminary assessment criteria, principles for responsible use of nanomaterials, and market transparency for consumers. A former participant emphasized:

> "the process itself was necessary and it was very helpful, because everyone had the possibility to talk about their problems, about their fears, and the others could give solutions. […] The idea was to separate those problems, which can be solved by the parties themselves. The dialogue meant that [some issues]

> have not popped up so high because [we] talked about it – so we didn't need to make the public aware of all the little problems we had."[1]

The NanoKommission provided a forum for regular exchanges among public authorities and private stakeholders and hence facilitated the formulation of agreed positions. Discussion allowed participants to develop a common diagnosis of the major challenges created by nanotechnologies, gather and disseminate information about scientific developments and debate the consequences of different policies and instruments; and the dialogue process has in turn help establish mutual expectations about the direction of German nanotech policy. Discussions within the NanoKommission have contributed to a more discerning societal debate with few signs of polarization thus far. This is not to suggest an exclusively consensual process, however. In chapter three, we for example saw how the views of UBA and VCI clashed over the issue of a German nanoregister. Members of the NanoKommission, who had been asked to analyze options for regulation based on the precautionary principle and – where possible – to make recommendations, were likewise unable to reach common ground – even on such fundamental issues as a definition of nanomaterials (NanoKommission 2010a; Grobe 2011). Observes a participant:

> "It was a dialogue. It was not necessary to have consensus at the end. It was necessary to say: 'we have consensus here, there and there, but not there.' That was okay. They were not forced to have consensus, because sometimes they know it is not possible. [The politicians did not say]: you have to go in like selecting the pope and we wait to see if the white smoke is coming out. That was not the point. The point was: sit together, talk about it and tell us at least what can you say. […] And even if we don't [agree to] fixed regulations, we have ideas about what we want and where to go. […] At least, it's important to be clear about what the others think [so you] have that in mind when you come together at a later stage."[2]

Although participants have not seen eye-to-eye on all issues, the NanoKommission did create opportunities for federal decision-makers to engage industry representatives in discussion and communicate their positions on and perceptions of different instruments and policy measures. Industry representatives for their part were thus able to learn how federal authorities understood and evaluated the available body of knowledge – and they therefore gained a better grasp of governmental intentions and ambitions for nanotech. By communicating information about federal agendas, priorities and preferences, the dialogue process in turn helped convince companies that regulators could be trusted with information about their operations.

1 Interview, Dortmund, October 11, 2012.
2 Interview, Dortmund, October 11, 2012.

The NanoDialogue was meanwhile supplemented – and often preceded – by parallel discussions in other venues. Major elements of the nanotech agenda have been channeled through existing advisory committees and stakeholder fora, in the process creating ample occasions for federal regulators to engage industry representatives in detailed technical discussions and debate possible prevention strategies. Consider consumer protection as an illustration. The BfR cultivates contacts with and inputs from external advisors through its 15 expert panel. Drawing their members from universities, industry associations, consumer and environmental protection associations, other public authorities and private laboratories, this expert network facilitates access to external expertise in support of risk assessments of food, feed, chemicals and consumer products. In chapter three, we for example observed how BfR drew on feedback from this network to inform its risk management strategies (Zimmer, Hertel and Böl 2010a). The BfR committees routinely bring industry experts together with their academic and governmental counterparts to debate current and likely future scientific and regulatory developments. The BfR committee for consumer products has for example discussed the use of nanomaterials in textiles at length and in great technical detail. By attending committee meetings, members gained access to up-to-date information on current developments as well as on the views and positions of other participants. The committee along with other BfR panels in other words provides a forum, where members can exchange information and experiences as well as learn about agency agendas and priorities, including how officials evaluate the need for new controls to mitigate possible risks to consumers.

We can glean additional insights into how deliberative institutions structure corporate risk-benefit calculations by turning to the German system of worker protection. Both the Federal Ministry of Labour and Social Affairs (BMAS) and the Ministry's technical arm, BAuA, routinely rely on expert bodies for advice on scientific and technical developments. Interactions under the Committee on Hazardous Substances (AGS) in particular exert a major influence on the formulation and implementation of worker protection in Germany. Constituted on a tripartite basis with representatives from Länder authorities, employers, unions and the statutory accident insurers, the AGS advises BMAS on all aspects of occupational safety and hazardous materials. An important element of the committee's work is therefore structured around the need to collect, analyze and evaluate scientific results and technical experiences. Under the Hazardous Substances Ordinance, the AGS is further responsible for elaborating occupational exposure values as well as issue specific protective standards. Given the pervasive risk uncertainties, nanomaterials have not surprisingly figured prominently among AGS's priorities. Questions of worker exposure have been raised on several meetings, and the committee is currently exploring mechanisms to

minimize possible risks. At its meeting in November 2010, the committee decided to initiate a rule-making procedure for activities involving nanomaterials (AGS 2011).

The AGS, then, supports deliberations of occupational safety issues and ongoing discussion of possible strategies for prevention, control and management of harmful substances. Regular meetings among a small group of experts encourage joint analysis of technical issues and scientific evidence. Conflicts of opinion, where they arise, are resolved through debate and negotiation. A BAuA official emphasized: "[in the AGS] we have a lot of consensus processes. […] We concentrate on dialogue, it is our idea. It is better to have joint ideas that everyone can stick to than to make regulations. We do regulation if it is necessary, but it is not the first idea to deal with these problems."[3] Although the AGS and its various subcommittees on occasion invite external expertise for specific issues and topics, meetings are not open to the public. Members of the AGS are in consequence able to resolve their differences out of the public eye and with little external interference from the competent minister or Parliament – a setup which favors and encourages candid discussions. Observers an industry representative:

> "[Our differences of opinion and interest are] not too big a problem, probably because we all know each other. […] Most of the problems arise because we haven't understood what we are talking about. But after you get everybody on the same level of knowledge, then it's much better to discuss and then you can discuss on a quite pragmatic [level]."[4]

Regular interactions channeled through the AGS and similar deliberative bodies in turn help improve corporate understandings of agency intentions and agendas. And they are therefore essential to convince German companies that federal official can be trusted with sensitive information. A VCI representative explained:

> "we always talk with each other very often – government, industry and others. We sometimes initiate [joint collaborations] without being forced by politics. Typically, people are on their job for 20 years, and they know each other. They know how the others are thinking, plus they have experience, which is very important. They know what they are talking about and understand the issue, and secondly they know the other people at least on a very good professional level […] and of course we can always call them and discuss [and say] 'why shouldn't we do it together, it is probably good for both parties'. And you know them for 20 years, you have trust in them, and you know [that] your partner is competent. Whereas in other countries, where you have a switch every 2 years, you neither establish professionalism in your professional subject or you don't get relationships where you have the trust to work on such projects."[5]

[3] Interview, Dortmund, October 11, 2012.
[4] Interview, Frankfurt, October 11, 2012.
[5] Interview, Frankfurt, October 11, 2012.

Advisory bodies and stakeholder fora provide institutional umbrellas under which personal relations and trust can develop among representatives from industry and federal authorities. And the formal advisory system thus acts to sponsor an undergrowth of informal discussions among ministerial officials, regulators and industry representatives. In chapter three, we saw how such discussions resulted in the joint BAuA-VCI industry survey and various other examples of collaborations. A BAuA official noted:

> "Working with the VCI is usual for us. We nearly always try to have partners [in our projects]. Our German idea of regulating is that we bring the employers, the representatives of the employees, the scientific persons and the authorities together and then make joint decisions […] From this idea, we usually try to find other persons, when we are discussing problems or are trying to solve them. And that is why when we are talking about nano, VCI was a good partner, because they know the industries, where they really use it, not where it is [only] an idea to use it. They are very, very active, so it was an idea to say: 'let's come together and make those things we have [now] done'."[6]

The German story of nanotech regulation thus illustrates that for regulators and industry representatives, who interact under the auspice of deliberative institutions, information disclosure need not be problematic. Ongoing deliberations have allowed industry representatives to learn how federal authorities interpreted the available body of knowledge – and therefore anticipate how authorities might react to new information. The extensive reliance on advisory bodies in deciding the course of German chemical safety policies is thus instrumental to underpin the credibility of bureaucratic commitments. An official phrased it succinctly: "In other areas, like industrial chemicals and biocides, there is always a dialogue with industry, in the general law-making process, but also in the specific authorization processes. With nano, it's just a very long-term discussion."[7]

DENMARK: ABSENCE OF A BASIS FOR DIALOGUE

Despite a comparable commitment to dialogue, discussions among state officials, government researchers and industry representatives in Denmark have not been organized around joint membership of deliberative fora. Relations among state authorities and industry have consequently remained detached and arms' length. The Danish nanotech story is however not one of antagonism, conflict or even deep-seated distrust of state authorities. It is an account though, of how the absence of institutionalized policy deliberations has tainted corporate

6 Interview, Dortmund, October 11, 2012.
7 Interview, Dessau-Roßlau, October 8, 2012.

confidence in the agendas, priorities and preferences of state authorities. With no permanent venues to organize and promote discussion of how the evidence for nanotech should be interpreted, there has been no clearing of mutual expectations and few occasions to develop common understandings of the challenges facing regulators and companies. Unlike their German competitors, Danish companies were presented with few opportunities to learn how state authorities understood the evidence and evaluated the need for new controls. And their cautious and acquiescent response to the regulatory process is thus rooted in uncertainty about governmental ambitions for nanotech.

Deliberative institutions do exist in the Danish chemicals sector. Danish regulators are no more than their German colleagues able to penetrate the arcane realms of science and engineering without the aid of specialists. Officials routinely seek the advice of experts to interpret the evidence of harm, to access international experiences or to estimate the effectiveness and cost of alternative control measures. State authorities likewise readily recognize the need to canvass the views of industry and other stakeholder groups. Advisory bodies and stakeholder fora are in short as much a feature of Danish environmental and worker protection policy-making as they are of the German policy-making environment. But while these deliberative fora operate with similar mandates as their German counterparts, their impact on corporate risk-benefit calculations have nonetheless been marginal: in Denmark, advisory bodies have not promoted dialogue and exchanges among state bureaucrats and corporate representative – and they have failed to do so either because they were discontinued; they did not invite industry participants; or because their mandate meant that nanotech is only now emerging as an issue of concern.

In chapter three, we saw that Danish policy-makers and regulators have not been oblivious to the value of dialogue as a means to inform decisions on the direction of national nanotech policy. With the aim of encouraging knowledge exchange and networking, a stakeholder forum, NaNet, was therefore established with public funding in 2005. Yet, although NaNet was created with much the same ambitions as the NanoKommission, albeit on a much smaller scale, the forum quickly ceased operations – just in fact as the nanotech debate began to gain momentum in Denmark. The termination of NaNet left regulators and industry without a forum, where they could meet on a regular basis to debate scientific developments, analyze the roots of joint problems and craft agreed solutions. Discussions have instead occurred on an infrequent and issue-specific basis. Both state authorities and trade associations have convened occasional 'dialogue' meetings. Such events of course have their merits, and participants have in general expressed satisfaction with this format. Unlike an ongoing dialogue process, however, these

meetings were merely meant to inform interested parties about international and national developments. Despite their name, 'dialogue' meeting have created only limited opportunities for participants to engage in detailed discussions of complex technical issues. We can illustrate by examining comparable experiences from Germany.

The German policy process has witness its share of open workshops and consultations on a wide range of specific topics. Federal ministries and agencies alike have all convened one-day conferences to identify consumer risks and perceptions, sources of occupational exposure and discuss the viability of different regulatory mechanisms. During interviews federal officials readily acknowledged the value of workshops as occasions for participants to present – in general terms – their views and positions. But such meetings the officials emphasized rarely encourage discussions of scientific data or how the results should be interpreted.[8] A similar observation applies to Denmark: dialogue meeting have seen information flow from state authorities to industry – but not from companies to regulators. Orientation meetings allowed state authorities to communicate their views to a wider audience. But because such meetings have been convened on an irregular and infrequent basis, Danish companies have been unable to keep abreast of how the rapidly evolving international nanotech debate might influence agency agendas and priorities. Without regular opportunities to learn how state bureaucrats understood scientific developments, corporate representatives had no reliable basis to inform their expectations about probable regulatory reactions. We are thus presented with a first clue to their cautious and subdued response.

A closer look at how state authorities have sought to cultivate expert advice allows us to unpack corporate risk-benefit calculations in greater detail. Just like their German colleagues, Danish officials have relied on external sources of expertise to inform their risk management decisions. State authorities have routinely sought inputs through informal contact as well as through standing advisory committees. The Danish Health and Medicines Authority's (Sundhedsstyrelsen) scientific advisory committee has for example demonstrated great concern for the human health and environmental implications of nanomaterials. Sundhedsstyrelsen and other state authorities rely on the committee to identify potential sources of harm and where possible recommend mitigation strategies. In this capacity, the committee is asked to gather, translate and disseminate scientific evidence and international experiences among participants, authorities and the public. As a platform for ongoing discussion of scientific assumptions and

[8] Interview, Dessau-Roßlau, October 8, 2012.

analytic judgments, industry participation might have afforded representatives from state authorities, academia and industry opportunities to develop a common diagnosis of nanotech. Unlike similar expert panels in Germany, committee membership is however confined to representatives from named academic and governmental research institutions. Representatives from industry are excluded. While the committee assists regulators access information and scientific interpretations, it does not bring experts from industry in close and permanent contact with their academic and governmental peers; and regulators cannot use the committee as a venue to discretely communicate their agendas and priorities to industry.

Beyond interactions under established advisory bodies, the Danish nanotech debate has been organized around MST's informal expert network. Members of this network have however been drawn exclusively from governmental research institutions and universities. Experts from industry have not participated in or otherwise contributed to their discussions, and they have thus been denied the same opportunities for 'a meeting of minds' as their German colleagues. The absence of an institutionalized dialogue has in turn inspired little confidence in the professionalism of academic and governmental experts. An industry insider voiced these frustrations:

> "They rely on their own contacts – one academic asks the next academic. They show little interests for reaching beyond their own circles and much less for how they might access 'hands on' experiences with these issues. Let me put it bluntly: academic 'reality' has long since been outpaced by commercial developments. We are so far ahead that they have about a snowball's chance in hell of catching up with us. The problem is that the authorities are not listening to us, because we are 'dangerous' – we are the bad guys. They listen to academics [who still] discuss how Adam met Eve in Paradise. It may sound grotesque, but I cannot help but think: 'wake up people! We know so much more than that.' And still they talk and get nowhere. […] They of all people ought to be asking: 'where is [nanotech] taking us and what regulatory response is required?' But my word no: they are looking to regulate, where we raced past them five years ago. And that is absolutely grotesque […] I do not know how many times I have thrown documentation, international studies, EU funded studies, REACH reports… I have thrown countless studies at the Environmental Protection Agency and the Working Environment Authority, at the regulatory decision-makers, at the universities, at the public authorities, even at the politicians to say: 'listen, the knowledge is already available!' How is it that no one in the Kingdom of Denmark has the capacity to absorb that knowledge? Because they sit in their own little pond and ask only the duck next door."[9] (*My translation*)

Absent consultation or exchanges among the group of academic and governmental experts and the industrial community, Danish companies were given few opportunities to learn about

[9] Interview, Copenhagen, June 1, 2011.

governmental ambitions and designs for nanotech; and their understandings of and expectations about possible governmental reactions were consequently hazy. But even where the Danish chemical control regime does institutionalize discussion, negotiation and collaboration among state authorities and industry – the system of worker protection – nanotech has not given rise to extensive deliberations of scientific evidence or possible control measures.

Worker protection is where the Danish chemical control regime most closely resembles the situation in Germany: the Danish Working Environment Council, Arbejdsmiljørådet (AMR), includes representatives from the social partners and serves to advice the Minister for Employment. AMR is responsible for drafting regulatory proposals and must be consulted prior to the promulgation of new statutory instruments. The Council monitors developments related to workplace safety in Denmark and gathers current information and international experiences about potential sources of harm. Like the AGS, AMR creates opportunities for members from state authorities, businesses, and unions to settle disagreements through discussion, develop common understandings and negotiate agreed solutions. The Council has nonetheless had little impact on the nanotech agenda in Denmark: the potential human health risks of nanomaterials have occasionally surfaced on Council meetings – but only as an issue that might warrant future attention. Members have requested that the Minister of Employment keep the Council informed of ongoing developments, but they have so far demonstrated little concern for or independent interests in nanotechnologies.

Like the AGS, AMR is focused on preventing workplace harm by formulating measures to reduce or mitigate sources of exposure. While the Council thus provides a forum, where members can meet to gather, share and discuss information, its mandate does not extend to the generation of evidence to support the identification of occupational hazards.[10] Members instead rely on state authorities to fund, organize and produce the basic research required for risk assessment and management; and the Council's agenda and deliberations is therefore intimately tied to the regulatory activities of the Danish Working Environment Authority (AT). Like authorities in other countries, AT has prioritized initiatives to build the knowledge base to evaluate the need for new regulations. The agency has in consequence looked to the National Research Centre for the Working Environment – an independent research institution under the Ministry of Employment – and more recently the Danish Centre for Nano Safety for advice on

[10] Phone interview, July 2, 2013.

possible occupational risks. But this approach also limited the role of AMR members in the nanotech debate.

Although representatives from NFA participate as observers in AMR meetings and may be asked to participate in the formulation of technical rules, there are few institutionalized contacts or exchanges among researchers from NFA and members of the AMR.[11] NFA initiatives and results have not been communicated to the Council on a regular basis and have therefore sparked only limited interest among its members. This lack of attention to nanotech is meanwhile reinforced by AMR's mandate: the Council must be consulted on new statutory instruments and AT does routinely seek inputs from members – once a decision to regulate is made. Members thus participate in policy discussions of reduction strategies or mitigation instruments. But AT alone decides which substances are taken up for review. While researchers at NFA now advocate the need for new regulations to control occupational exposure to nanomaterials, AT has indicated that new measures must await the conclusion of ongoing discussions at the European level. Short of issuing new binding rules, the agency instead published statements in May 2013 intended to clarify the responsibilities of employers.

With AT restricting its activities to building the evidence, there has been little reason for Council members to discuss nanotech. Since the nanotech agenda in effect has been funneled around – not through – the AMR, members were given few occasions to learn how officials at AT understood the evidence and evaluated the need for future controls. Although the AMR thus demonstrates a capacity for deliberation, negotiation and consensus among state authorities and the social partners, the Council has had little impact on business expectations about the probable responses of state authorities. Insulated bureaucratic decision-making processes broken only by *ad hoc* consultations in short left Danish companies without a sense of the bigger picture. And they therefore reacted cautiously to governmental appeals for cooperation.

THE ROOTS OF GERMAN AND DANISH BUSINESS RESPONSES

Variations I submit in the capacity to predict the probable reactions of state bureaucrats explain the varied responses of German and Danish companies. In Germany, regular contacts and policy deliberations among federal decision-makers, companies and their representatives have focused on closing existing knowledge gaps, on interpreting the available evidence and ultimately carving

[11] Phone interview, July 2, 2013.

out a regulatory response to ensure the safe and responsible development of nanotechnologies. Since discussions were embedded in a dense network of advisory committees and similar deliberative fora, German companies were presented with ample opportunities to learn how federal decision-makers understood the evidence for nanotech and how they evaluated the need for new controls. The dialogue process helped industry gauge the intentions of federal authorities, and it in turn bolstered corporate confidence that their views and interests would be considered and respected. Knowledge about the designs and priorities of federal authorities thus helped dispel possible misgivings in their commitments. Since information is instrumental in shaping regulators' interpretation of the evidence, their diagnosis of and solutions to regulatory problems, this confidence created compelling incentives for companies to volunteer their expertise and experiences to federal officials. Disclosure and dialogue have in other words permitted industry to shape the direction of German nanotech policies. An official observed:

> "It is always a compromise which comes out in the end. It is tit-for-tat in a way: you get information, you know what the industry is working on, you know their interests, and on the other side […] the companies then know what the federal agencies need or what they want to know. [Companies] can influence the public authorities [by saying:] 'don't make [the regulations] that strict.' It can work fine, because you get a regulatory system, which can work."[12]

Danish companies have in contrast enjoyed few occasions to learn how state bureaucrats understood and evaluated the available body of evidence. While deliberative institutions do exist in Denmark, the policy process did not accord representatives from state authorities and industry regular opportunities to debate scientific developments, develop common understandings, and reach agreed conclusions. Laments an industry insider:

> "Denmark lags far behind other countries and the so-called experts simply do not have the necessary knowledge and understanding [of these issues]. The problem in Denmark is that we – the commercial stakeholders – are not consulted. […] We do not influence the agenda and we are not heard by the politicians or the authorities. We are only heard, when the media is thrown a bone. […] Because we have commercial interests, we are considered 'dangerous'." (*My translation*)

Companies were in consequence left without a reliable basis to predict how state authorities might react to new information – and whether and how such a response might consider their views and interests. A cautious and timid stance was therefore a sensible response to the policy process; and reluctance to volunteer sensitive information to state authorities a strategy to minimize the economic and administrative impact of decisions over which companies had little influence. We can illustrate the precarious position of Danish companies with the decision to

[12] Interview, Berlin, June 22, 2012.

introduce a mandatory nanoregister. In March 2011, a MST official observed: "There has been a discussion of separate regulations for nanoproducts. At the moment, we do not see the need for new regulations, because there is no evidence that nanomaterials should be treated any different than other substances. Then again, you never know…"[13] (*My translation*) 18 months later a nanoregister was a reality in Denmark.

While the decision to introduce registration obligations reflects part of a political compromise over the 2012 national budget, MST's position and preferences on a nanoregister had also shifted. Rejecting arguments from industry that the 2007 mapping exercises had succeeded in generating needed and sufficient information – and that statutory requirements in consequence were futile and unreasonably burdensome for industry – MST (2012: 11) noted:

> "Experiences with voluntary reporting in for example the UK as well as the projects undertaken in Denmark […] have shown that [voluntary] approaches are insufficient to provide an overview of the number of nanoproducts in commerce. A mandatory reporting requirement is therefore considered proportional." (*My translation*)

Prior to March 2011, companies had been given few reasons to expect that Denmark would be among the first countries to introduce mandatory obligations for manufacturers and users of nanomaterials. MST had raised – and dismissed – the possibility of a reporting requirement at previous orientation meetings. Since however decisions on the direction of Danish nanotech policy were informed by discussions among a closed group of governmental and academic experts, industry was not presented with indications that the evaluation of a nanoregister was changing. Because industry representatives did not participate in these policy deliberations, they in short had little basis to predict a reversal of the agency's position of a nanoregister.

Despite the disparate nature of the German and Danish nanotech experience, some overlap does nonetheless exist. In chapter three, we for example observed how UBA's attempt to encourage companies to volunteer information met a silent response. Because it sheds further light on the conclusions reached in chapter four, we will briefly dwell at the roots of UBA's 'uneasy' relations with industry. The weakest of the federal agencies, UBA serves mainly an advisory role to the BMU and other federal ministries. The creation of UBA in 1974 was widely interpreted by the chemical industry as "a signal that the government was no longer going to depend exclusively on 'the closed circle of experts' for advice on the formulation and implementation of environmental policy, but was going to go beyond industry and the

[13] Interview, Copenhagen, March 9, 2011.

established scientific community for advice." (Paterson 1991: 231) Viewed as a competing source of expertise, industry came to adopt a belligerent stance towards the new agency.

UBA is endowed with few statutory powers, but must rely instead on its powers of persuasion to influence regulatory outcomes. Recall that the ambiguous delegation of regulatory powers in U.S. chemical control legislation implies that American companies seldom look to the federal agencies to advance their interests. Fragmentation of powers affords companies alternative routes of influence and they often see little value in maintaining relations with regulators on congenial terms. A comparable situation exists for UBA. We can illustrate with the German debate over a possible nanoproduct register. Intensely debated during the NanoKommission's second phase, no consensus on the need for or design of a register was reached. While the idea found support among environmental and consumer organizations (NanoKommission 2010c), VCI and other industry groups flatly rejected mandatory requirements "on the grounds of overlap with existing registries, the complexity, the high administrative costs and the risk that consumers could perceive this as a sign of unexplained or general risks inherent to all nanomaterials or 'nano-products'." (VCI 2011) (*My translation*) Described as a 'touchy subject' by observers,[14] a nanoproduct register ultimately won little political support. Although the Environmental Minister appeared in favor of introducing reporting obligations, "not much happened, because he didn't have support from the other resorts in government – the Ministry of Economics for instance or the Consumer Ministry didn't support him."[15]

Despite UBA recommendations, and BMU's more 'progressive stand on nanotech regulation',[16] opposition from other ministries served to thwart a compromise. The ensuing stalemate within the Federal Government draws our attention to what has in the past been a well travelled avenue of influence for industry. Like their UK competitors, German companies could rely on their capacity to persuade ministerial officials sympathetic to the views of industry to defend their interest. Because political decisions – whether on a nanoregister or chemical safety policy – must be cleared through interdepartmental coordination and negotiations, the VCI and its members has often managed to place a break on 'meddling' bureaucrats from the environmental administration by convincing the BMBF and especially the powerful Ministry of Economics to intervene on their behalf (Grant, Paterson and Whitston 1988). BMWi still insists

14 Interview, Berlin, June 22, 2012.
15 Phone interview, October 30, 2012.
16 Phone interview, October 30, 2012.

and ensures that industry is consulted prior to the launch of new initiatives;[17] and as illustrated by the debate over a German nanoregister, this situation translates into generous opportunities to indirectly influence the direction of chemical control policy. Since the chemical industry is thus afforded alternative routes of influence, companies have found little need for or value of attempting to cultivate close and cooperative relations with regulators from UBA.[18]

But the reluctance to share information with UBA officials also demonstrates a lack of confidence in the intentions of an agency traditionally viewed as competing source of expertise. Unlike BAuA or BfR, UBA does not entertain an institutionalized dialogue with industry. UBA does look to advisory bodies for expert inputs – none of which however includes members from industry. Officials do not engage industry representative in routine discussions about potential sources of environmental harm or their possible solutions – such discussions are instead organized and sponsored by UBA's resort ministry, BMU.[19] UBA has – like authorities in Denmark – in effect limited its interactions with industrial stakeholders to occasional conferences and issue-specific consultations. Although UBA officials did participated in discussions under the NanoKommission, disagreements often emerged among UBA and NGOs on one side and industry on the other. Despite the general pattern of collaborative interactions among federal entities, German companies and their representatives, UBA's experience in short mirrors the Danish nanotech story. Absent secure channels to communicate the agency's agendas and priorities, UBA has been unable to convince German companies to volunteer information.

The gentle reader might object that this account neglects the most enduring source of divergence between the German and Danish chemical industries: their vastly different sizes. Whereas the chemical industry was an economic powerhouse of postwar Germany, the same cannot be said for its Danish counterpart. Although moderately successful in economic terms, the Danish chemical industry dwarfs in international comparison. Germany leads in Europe by the number of companies commercializing nanotechnologies – the industrial uptake of nanotech in Denmark barely registers in comparison (BMBF 2009; 2011b; Andersen and Rasmussen 2006; Tønning and Poulsen 2007). The different experience, scale of operations, and importance of the chemical industries in the German and Danish political economies clearly hold implications for their political options and behavior. An alternative reading of the German and Danish nanotech stories might – in an echo of Peter Katzenstein (1985) – therefore run along these lines: Whereas

17 Interview, Dessau-Roßlau, October 8, 2012.
18 Interview, Dortmund, October 11, 2012.
19 Interview, Dessau-Roßlau, October 8, 2012.

the large and powerful German chemical industry can shape and bend the rules – in Germany, in Europe and globally – to its advantage, smaller industries have few options, but to swim with the tide. Given its diminutive size, the Danish industry must in short take, not make the rules that governs its conduct. German and Danish companies thus had very different stakes in governmental decisions concerning nanomaterials – a fact that explains why Danish companies have not demonstrated greater interest in and concern for the regulatory process.

The size of national industries does undeniably influence their political options and behavior. Rather than view this as a problem for my account of business responses in Germany and Denmark, I suggest that we might instead understand it as an opportunity to explore the absence of institutionalized policy deliberations among state bureaucrats and Danish companies. To unpack this narrative, we need to make a brief detour to explore historical patterns of chemicals regulation in Denmark, past interactions among state bureaucrats and chemical companies and how this has influenced their reactions to state intervention.

Although chemicals are indispensable for industrial production, the core chemicals sector does not represent a major branch of Danish manufacturing industry. Denmark has no production of basic chemicals of note and the industry consists almost exclusively of downstream users and distributors of imported chemicals. Small and medium sized enterprises specialized in intermediate and end products dominate the Danish chemicals sector. The industry's weak economic basis and fragmented structure translated into weakness in political terms. The interests of the Danish chemical industry have found no ministerial champion comparable to the BMBF or the powerful BMWi. Unlike the agrichemical industry, which could count on the Ministry of Agriculture to defend its interests – where they coincided with those of farmers – producers and industrial users of chemicals were left to fend for their own interests. Since the state had no significant industry to protect, decisions to intervene in the affairs of the chemical industry were not moderated by the need to accommodate major producer interests. Denmark has in consequence often been among the first countries to restrict problematic chemicals (Boye and Ege 1999). The absence of major manufacturers and strong producer interests on the other hand also meant that Danish chemicals policy is characterized by continuity of preferences and priorities. Control policies changed little from one government to the next; and Denmark has been spared many of the protracted controversies, which have riddled countries, where producer interests are more dominant.[20]

[20] Interview, Copenhagen, March 9, 2011.

The industry's relative economic and political weakness in turn gave rise to a distinct pattern of interactions among its representatives and state bureaucrats. Lacking the economic weight of their German competitors, Danish companies did not have the political strength or resources to pry open administrative proceedings or demand representation on scientific advisory panels. State agencies seldom sought the advice of industrial experts to support hazard identification and risks assessment; instead, they relied on the expertise of academic researchers to evaluate and interpret scientific evidence. Drawing on international experiences and knowledge generated by public research institutions, decisions on whether and when the state should intervene to restrict specific chemicals have *de facto* been left to state bureaucrats. Companies accepted that initiative rests with the state, and the relevant question has instead been how to adapt to and if possible benefit from state intervention.

While this pattern can be traced to the early reaches of the 20th Century (Steensberg 1981), it was formalized with the 1979 Chemicals Act, which consolidated the state's responsibilities for chemical safety. Unlike the pesticides area, where the act created an advisory board with representatives from agriculture, pesticide manufacturers, and civil society organizations, similar arrangement for industrial chemicals were rejected. In the negotiations preceding the enactment of the Chemicals Act, the Ministry of the Environment effectively opposed proposals to establish an advisory committee with a pluralistic or corporatist composition. The Ministry instead insisted on separating expert advice from the articulation of partisan interests, fearful that a procedure which granted access for industry expertise might blur the boundaries. While the negotiations saw the Ministry of Agriculture intercede to guarantee representation for agrichemical companies on the newly established council for pest management products, manufacturers and users of industrial chemicals had nowhere to turn for support. Without the backing of a ministerial sponsor, the chemical industry had little choice but to accept the position of the Ministry of Environment (Jensen 1983).

Rather than institutionalize policy deliberations among state authorities and industrial stakeholders, the 1979 Chemicals Act demonstrated a clear preference for building bureaucratic expertise in the areas of toxicology, eco-toxicology and epidemiology – a preference which resurfaced throughout the 1980s and 1990s. In the debates over biotechnology, for instance, the Environment Ministry again chose to develop in-house expertise rather than institutionalize access for industry representatives through a standing advisory committee (Levidov 1998). Although stakeholder fora have since been established for specific sectors or product areas, such as electronics, textiles or construction, a forum where representatives from academia, industry and authorities could meet and discuss issues pertaining to industrial chemicals was never created.

Proposals to establish such a permanent venue have been rejected – often with arguments that echo the Environment Ministry's initial resistance to a pluralistic advisory committee (see *e.g.* Teknologirådet 1999).

Accepting state initiative however also came easier for an industry which had no strong vested interests in the manufacture of specific chemicals. Since control policies often sought to temper the disruptive impacts of substance bans or use restrictions through generous transition schemes, the economic stakes for industry were seldom sufficient to induce fierce mobilization. With virtually all chemicals imported for use by small and medium sized enterprises, Danish companies lacked the resources – and incentives – to develop the requisite knowledge and expertise to penetrate administrative risk assessment proceedings. A VCI representative was adamant about the implications: "You need the expertise of the big companies. [Small companies] don't have the expertise. They don't have the manpower."[21] SMEs abound in the Danish chemicals sector, but there are no major chemical corporations with production capabilities or facilities in Denmark. Large international manufacturers do operate on the Danish market, but their activities are limited to distribution. Whereas the Danish chemical industry in other words lacked the economic resources to invest in general scientific knowledge and expertise, its larger German competitor in contrast allocates significant resources to chemistry science and related fields. Based on member contributions, the VCI for example administers the *Fonds der Chemischen Industrie* to support basic scientific research in universities. These commitments have not only helped build industrial expertise and scientific capabilities, but have also resulted in close links and long-standing sympathies among industry and the academic community (Martinelli and Grant 1991: 281).

Because Danish companies in general do not manufacture their own chemicals – but rely on substances imported from upstream suppliers – they also faced fewer incentives to learn about their possible adverse effects. Chemicals manufacturers have vested interests in their substances, and they therefore have good reason to learn as much as possible about their effects (Applegate 1991: 299). The manufacturer's costumers – the industrial users – however have very different stakes in the substance. While a particular chemical may constitute an essential component of the users' production processes or products, their responsibilities for the substance is nonetheless limited. Adverse effects – provided the guidance issued by the supplier has been followed – seldom create major liabilities for the user; and if so they can often be circumvented by looking

[21] Interview, Frankfurt, October 11, 2012.

for suitable replacements. Although restrictions on use or mandatory substitution obviously are not desirable from a user perspective, the financial implications and technical impediments are nevertheless minor compared to the manufacturers that might be forced to rethink and redesign their substances or processes entirely, suffer significant losses of revenue or worse have to cease production all together. As downstream users, then, Danish companies had little need to invest in scientific expertise, develop independent understandings of the properties of their imported chemicals, and fewer reasons still to undertake – expensive – testing and analysis. Whether the question is bulk chemicals or nanomaterials, the major source of information about possible human health and environmental effects for Danish companies thus remains their suppliers – and state authorities.

Given its structural characteristics, the Danish chemical industry in short had neither the resources nor incentives to develop the expertise and knowledge necessary to penetrate administrative risk assessment proceedings. With little privileged knowledge relevant to hazard identification or the requisite expertise to deliberate analytic assumptions and scientific judgments, access to the advisory process held little promise of influence. Danish companies instead resigned to await state initiative. State bureaucrats for their part showed little inclinations to seek the advice and judgment of industry in identifying problematic chemicals. Deliberations among experts from state authorities, academic institutions and industry were therefore never institutionalized as a mechanism to promote consensus on difficult-to-resolve scientific or technological issues. For German companies in contrast participation in administrative risk assessment procedures constitutes an opportunity to mold the knowledge and understandings of federal bureaucrats. Rather than resign to state initiative, institutionalized deliberations among industry and federal authorities create opportunities to shape and divert decisions to intervene against specific chemicals. In this sense – the political weakness of the Danish chemical industry and its structural reliance on the knowledge of suppliers – it is therefore correct that the vastly different sizes of the German and Danish chemical industries influenced their disparate responses to nanotech. Since Danish companies do not participate in decisions to regulate specific chemicals – whether bulk or nanoscale – their acquiescent response to the regulatory process is perhaps to be expected.

Does this mean that Danish companies had no information of value to the regulatory process – and no concern for its outcome? Of course not! Notes an observer:

> "It may well be that we do not quite understand the risks. But that is no excuse for not knowing how may Danish companies [are working with nanomaterials], what materials they use, how many workers are exposed, what products are available, which materials are used in those products, in what concentrations and so on. All this basic information, which you also need to do a risk assessment, this information has

> not been compiled. Say you were to discover that certain nanomaterials were absurdly problematic – then you would have no idea about where in the consumer and production chains they are used and who the Danish manufacturers might be. And that is problematic to say the least."[22] (*My translation*)

State authorities posed these questions to industry. Companies knew the answers – but showed only limited appetite for disclosing the requested information. I have argued that discomfort in the intentions of state bureaucrats explains this response. With the benefit of the historical context for chemicals regulation in Denmark, we are now in a position to further elaborate corporate risk-benefit calculations and the roots of their subdued response.

In chapter three, I mentioned that the Danish chemicals sector is governed by consensus and inclusion of affected interests. This is in part an expression of a wider corporatist legacy: negotiations and compromises with organized interests were encouraged to facilitate parliamentary approval of new legislation and its subsequent implementation (Andersen, Christiansen and Winter 1998; Christiansen, Nørgaard and Sidenius 2004). But it also reflects how decisions of chemical control policy depend on inputs from industry. In the words of a MST official:

> "It is very difficult for us here at *Miljøstyrelsen* to target activities for regulation unless we have some understanding of what is happening on the ground. But from behind my desk, you simply got to acknowledge that our understanding of what actually goes on at some factory is rather limited. So we need to talk with those who have that understanding. […] Unless you talk to the parties, there is a very, very good chance that you'll draw up something which either doesn't work or else has some completely unintended consequences, which means that you'll have to do it all over again."[23] (*My translation*)

Responsibility for the identification of chemicals hazards may well rest with state bureaucrats. But that still leaves the important question of how the state should intervene to control those hazards. Because the effectiveness and cost of alternative control measures are difficult to estimate, regulators necessarily seek guidance from those with the requisite technical expertise, information and experience – in effect the companies working with the chemicals regulators are looking to control. Despite its diminutive size, state authorities have routinely negotiated the design of statutory instruments with representatives of the chemical industry. Rather than question administrative decisions to intervene against specific chemicals, companies have instead focused their efforts on shaping the choice of statutory instruments. Companies can in short countenance state initiative, secure in the knowledge that the instruments of intervention are subject to negotiation and – often – compromise.

[22] Interview, Copenhagen, May 31, 2011.
[23] Interview, Copenhagen, March 9, 2011.

Nanotechnologies thus presented Danish companies with a familiar situation: as state authorities were gathering evidence in support of a decision to intervene or not, companies had little reason to mobilize – knowing full well that disclosure would not significantly influence or alter this decision. Biding their time, nondisclosure was in contrast attractive from a corporate risk-benefit perspective: should state bureaucrats decide *not* to intervene – all the better for industry. Should state authorities – as they indeed did – decide that new regulations were required and justified, corporate interests might be better served by withholding information until their representatives were called upon to negotiate the terms of intervention.[24] While business associations thus have voiced few opinions on nanotech, the first real display of concern came with the decision to introduce a nanoregister. Industry had no say in this decision and was unable to divert its passage through Parliament. Yet, while the bill empowers MST to introduce a reporting requirement, it did not specify the design of this requirement. Questions of the number and type of products subject to registration, possible exceptions, the definition of nanomaterials, the frequency of registrations, the scope and extent of information required for registrations, data access and protection of confidential business information *et cetera* were all left to administrative discretion – and were therefore open to negotiation. At the time of writing – August 2013 – discussions among MST officials and industry are still ongoing and speculations concerning their eventual outcome are probably unproductive. Yet, while Danish companies were unable to prevent the creation of a nanoregister, they are now nonetheless in a position to influence its scope, design and implementation. Since their capacity to persuade state bureaucrats will depend on the arguments, information and expertise they bring to the negotiations, their interests were better served by not disclosing it prematurely. Although in short the diminutive size of the Danish industry undeniably influenced its response to the regulatory process, it did not determine that response. The industry's political and economic weakness, and its structural reliance on information provided by upstream suppliers, is rather a precondition for understanding the roots of the acquiescent and subdued responses of Danish companies.

BRITAIN AND THE UNITED STATES REVISITED

This account of German and Danish business strategies differs from the explanation I offered for their Anglo-American competitors in chapter four. There I argued that concentration of

[24] Interview, Copenhagen, May 31, 2011.

regulatory powers in state bureaucracies explain their capacity to commit to cooperation with industry; and I demonstrated how variations in bureaucratic autonomy account for the varied responses of American and British companies. Both accounts depart from the premise that business responses grow from expectations about the probable behavior of state bureaucrats. Because they transmit information on the intentions, agendas and strategies of regulators, the configuration of institutions and processes of chemical control regimes help companies formulate strategies to anticipate regulatory risks and opportunities. But the two accounts identify different sources of information about the possible reactions of state bureaucrats: in chapter four, I demonstrated how companies use their understanding of formal institutions and their operating procedures to predict probable outcomes. In this chapter, I have in contrast emphasized how repeated historical experience builds up a set of common expectations that allows companies to anticipate how regulators will react to new information.

Are there points of tangency between these two accounts? As I mentioned above, the legal and institutional relationships found in the German and Danish chemical control regimes are roughly comparable and thus cannot – with the exception of UBA – be the source of the variation we observe. State bureaucrats are in both countries empowered to determine what chemicals to regulate, in what order, by what means, and how stringently. Scrutiny by national parliaments or the courts rarely infringes on bureaucratic autonomy. As in Britain, concentration of regulatory powers and the limited prospect of political or judicial interference in short dictate a strategic orientation towards the bureaucracy. But how does the Anglo-American nanotech experience look in the German-Danish mirror? What role if any has institutionalized policy deliberations had for corporate risk-benefit calculations in Britain and the United States? Deliberative institutions as it were are an important – and so far neglected – element of the UK nanotech story; in the U.S., their impact on business responses has in contrast been negligible.

Advisory bodies abound in the UK chemicals sector – some of which are familiar from chapter three. Some two dozen expert committees and stakeholder fora advice HM Government on questions related to chemical safety and regulation. Governmental departments and agencies have routinely relied on these advisory bodies for guidance and inputs on their nanotech related initiatives and policies. Since industry is represented on many, if not most, of these advisory panels, the UK policy process has created ample opportunities for corporate representatives to engage decision-makers in regular discussion of governmental agendas, priorities and preferences. We saw for example how, in an effort to promote knowledge exchange and consensus on the direction of UK research policies, membership of the various taskforces under the inter-ministerial Nanotechnology Research Coordination Group was expanded to include

representatives from industry; and how deliberations among governmental scientist, academic researchers and industry experts helped guide decisions on research initiatives and priorities as well as facilitate agreement on the major challenges facing reliable hazard and risk identification (Defra 2007). The NRCG has thus provided a venue, where members could develop a common diagnosis of nanotech and gather information about the consequences of different decisions. Membership of the taskforces in turn created opportunities for industry representatives to learn how governmental decision-makers understood the available body of knowledge.

We also noticed how the Health and Safety Executive funneled discussions with corporate representative and industry experts through its network of advisory committees, boards and industry councils. Organized and operating according to similar principles as comparable German expert bodies, HSE relies on its advisory committees to engage industrial stakeholders in regular deliberations of industry drivers, workplace hazards and exposures. The Working Group on Action to Control Chemicals (WATCH) illustrates: following the conclusion of the October 2004 stakeholder symposium (HSL 2004), HSE asked WATCH members to review current knowledge about safety issues and advice the agency on the adequacy of existing exposure control strategies. WATCH members since engaged in detailed analyses of occupational health aspects of nanotechnologies with positions on toxicological hazard, occupational exposure, risk assessment and management approaches agreed among members (WATCH 2005; 2006; 2008).

WATCH and its sister committees have thus encouraged regular communications among HSE officials and industry representatives on sources of workplace harms as well as strategies for prevention, management and control. HSE's advisory committees serve as permanent fora, where officials can meet with experts from industry and other stakeholders to discuss the main health and safety issues facing particular industries and to consider methodologies relevant to best practice solutions. HSE further relies on its committees to translate and disseminate agency agendas and priorities to their constituent industries. And as we saw in chapter three, feedback from policy discussions often act as a stimulus for identifying industrial health and safety research needs. Because industry experts are placed in permanent and close contact with their academic and governmental peers, companies are in short better able to understand how the agency views and interprets scientific evidence of occupational harm as well as the need for new control measures.

Defra has likewise relied on its Advisory Committee on Hazardous Substances (ACHS) for advice in support of the ministry's nanotech related initiatives, investments and programs. Defra for example asked members to review information submitted under the VRS. Submissions were discussed and evaluated behind closed doors to accommodate the interests of data owners.

Members ultimately concluded that the information did not present cause for concern and were thus instrumental in persuading Defra that no urgent measures were needed to curb human and environmental risks.[25] Because the ACHS procedure preserves discretion and protects the privacy of communications, regular interactions among Defra officials and industrial members as illustrated by the VRS facilitates frank discussions about potential hazards and exposure; and the ACHS has since 2005 constituted a major source of advice on domestic and international developments related to nanotechnologies.

The ACHS further acts in support of the UK Chemicals Stakeholder Forum. Establish under the 1999 UK Chemicals Strategy (DETR 1999) to build trust among government, industry and other stakeholders, the forum was created to allow industry expertise and views to flow into the formulation of policy and priorities. The forum advises HM Government on how industry can reduce possible risks from hazardous chemicals, and reflects a measure to promote and institutionalize regular discussion among officials and industry representatives. As I observed in chapter four, the Chemicals Strategy cements past commitments to cooperation and dialogue with industry. Collaboration among UK companies and state authorities thus builds on and reflects a broader pattern of institutionalized policy deliberations in the UK chemical safety area.

While HM Government has turned to established advisory bodies and familiar contacts within the industrial community to garner advice and inputs, the fledgling nature of the nanotech industry also created its own set of problems. One official explained,

> "the main problem has been identifying who 'they' are in fact. Because of course they are the ones who make the nanocovers and the nanoparticles and they are quite obviously nanomanufacturers, but what about the people, who makes the paints with the nano-titanium dioxide, what about the people who do micro and nano-electronics? A lot of these people don't see themselves as nanomanufacturers and it is difficult to talk to the entire industrial community."[26]

In 2005, Defra therefore set up a Nanotechnologies Stakeholder Forum (NSF). The NSF brings together stakeholders from industry, academia and civil society organizations to ensure that wider concerns and perspectives are built into early policy deliberations (NSF 2005). Never intended as a mechanism to secure general consensus, the forum was instead meant to capture a wide breadth of opinions.[27] Initial meetings in the NSF were structured around the desire to discern the need for immediate action, while laying out governmental strategies and priorities. Both the VRS and other policy initiatives were for example subject to stakeholder deliberations

25 Interview, London, March 3, 2011.
26 Interview, London, March 3, 2011.
27 Interview, London, March 3, 2011.

prior to their launch. The NSF has allowed HM Government to float ideas to stakeholders and in return receive feedback on the design, formulation and implementation of regulatory measures and research initiatives. As "a valuable means of information exchange on developments in nanotechnologies" (HM Government 2009: 8), the NSF has thus underpinned regular policy deliberations among government and stakeholders. As one Defra official concluded, "the forum has been a very useful group up until now. It has helped shape policy, has helped us understand better what public perceptions are in the world of nanotechnologies."[28]

For UK companies, the NSF helped address uncertainties about the future directions of governmental policies and strategies. Informal discussions with officials served as a valuable source of information on their current statutory responsibilities. The forum has further helped UK companies keep abreast of how the rapidly evolving international nanotech debate might influence regulatory agendas and priorities. As a forum, where members could develop common understandings of complex technical issues, gather and share information about the consequences of different decisions and build mutual expectations, the NSF was thus instrumental to dispel possible concerns about the intentions of state bureaucrats. The reliance on informal consultation of UK companies and regular discussion with their representatives funneled through the NSF and similar deliberative bodies in short facilitated their ability to anticipate how state authorities might react to new information. Knowledge about the agendas of state bureaucrats in turn helped persuade companies that their views and interests would be considered as new issues emerge; and strengthen their beliefs in the credibility of bureaucratic commitments.

Business responses in the United States were in contrast colored by misgivings about agency intentions and agendas. Despite generous opportunities for American companies to participate in regulatory proceedings, there are few occasions for their representatives and federal officials to develop mutual understandings, craft common solutions, or reach agreed conclusions. While federal entities such as the NNI or EPA have placed great emphasis on getting all relevant parties to the table to ensure full public participation in the development of U.S. nanotech policies (Marchant, Sylvester and Abbott 2007), they have nonetheless been reluctant to draw in external views during the formative stages of decision-making. A stakeholder forum comparable to the NSF was for example never established in the United States; nor was industry representatives asked to join in deliberations with federal officials organized under the NEHI group. Examples

[28] Interview, London, March 3, 2011.

of deliberative institutions are thus few and far between, and representatives of organized interests have been kept at arm's length. Where deliberative institutions do exist – federal advisory committees – they have not created the basis for regular discussions among officials and industry representatives; and their impact on corporate risk-benefit calculations has been negligible.

Federal decision-makers have expressed interest in improving communication with companies and industry groups. Since the initiative's inception, the NNI has for example experimented with various mechanisms to tap the research needs of industry: between 2003 and 2005, NNI sponsored the creation of liaison groups with the electronics, forest products, chemicals, and industry research management communities. Described as mechanisms to encourage ongoing dialogue with industrial stakeholders,[29] these Consultative Boards for Advancing Nanotechnology (CBAN) brought public and private sector experts together in an effort to facilitate debate of NNI research programs and priorities. But while the CBANs did help structure dialogues among industrial stakeholders and federal officials (Maynard 2006: 37), their activities had ceased by 2007. The NNI instead came to rely on a more *ad hoc* format with discussions organized around a series of workshops and formal consultations. While an argument certainly can be made in favor of public workshops, they cannot substitute for ongoing discussion of complex technical issues. In their review of the NEHI research strategy, the National Research Council (2009: 8) for example found that while the

> "NNI reports have undergone public comment […] public comment is not the same as engaging stakeholders in the process. Without adequate input from external stakeholders, it is not possible for government agencies to develop an effective research strategy to underpin the emergence of safe nanotechnologies."

In chapter four, I explained how rigorous procedural and judicial controls of administrative discretion undercut bureaucratic autonomy. The NNI's now all but forgotten experiment with the CBANs illustrates how such controls also limits the ability of federal decision-makers to institutionalize deliberations with their industrial constituents – and therefore undermine the credibility of their commitments. Explains a NNI official:

> "we have some restrictions by the Federal Government for seeking advice from external stakeholders on a regular basis. We can't set up a regular series of advisors without going through a lot of rules […] at that time the lawyers felt that [the CBANs] were legal mechanisms to engage industry. But our laws and how

[29] Interview, Washington, D.C., April 23, 2012.

> our laws are interpreted change over time [and] the CBANs really are not legal under the current interpretation of the law – they violate FACA!"[30]

Passed during the 'Good Government' era of the 1970s, FACA or the Federal Advisory Committee Act is designed to formalize and routinize the use of advisory bodies, in part out of concern that some interests had come to enjoy unchecked and perhaps illicit access to federal decision-makers (Croley and Funk 1997: 453). The act stipulates that membership of advisory committees and their functions must be balanced and representative. FACA therefore precludes the creation of single stakeholder committees – like the CBANs. Establishing advisory bodies under FACA is a cumbersome task and U.S. regulators often look to arrange interactions with stakeholders in ways that avoid its requirements, *e.g.* through open workshops or *ad hoc* meetings. Although federal decision-makers thus have sought the advice of external experts to interpret the evidence of harm and access international experiences, they were also reluctant to create a platform – to 'go through the rules' – to structure discussions with stakeholders. With no permanent venues to organize and promote discussions of how the evidence for nanotech should be interpreted, there has been no clearing of mutual expectations over the direction of federal nanotech policy.

While the NNI has been mired in a search for appropriate dialogue mechanisms, the executive agencies have meanwhile turned to existing advisory bodies for inputs on matters pertaining to their statutory mandates. EPA for example called upon its National Pollution Prevention and Toxics Advisory Committee (NPPTAC) to advise the agency on an overall risk management approach to nanotechnologies. Federal advisory committees are constituted to bring needed expertise to the decision-making process; and – in theory – they are expected to provide a forum for technical experts to reach consensus on difficult-to-resolve scientific or technological issues (Ashford 1984). Reality on the ground is however often more complicated. While discussions among NPPTAC members for example did provide initial inputs for the NMSP (NPPTAC 2005a; 2005b), EPA's attempts to maintain a constructive dialogue with stakeholders quickly foundered. In response to agency policies on nanomaterials, the National Resources Defense Council and several other members decided to resign in protest, and in August 2007 EPA announced that the NPPTAC had completed its charged and that further activities in the committee would cease.

EPA's experience with the NPPTAC illustrates one of the major drawbacks of the federal advisory system: since FACA stipulates that membership must be balanced to ensure that all

[30] Interview, Washington, D.C., April 23, 2012.

major views are represented, advisory committees often prove incapable of reaching agreed positions. As I explained in chapter four, the adversarial format of regulatory proceedings demands that private interests present their views as strongly as possible. But the combative relations among competing interests and their belligerent stance against public officials rarely lend themselves to a search for compromise solutions. A federal official observed: "In Europe, people tend to see this more as a cooperative problem. We need to sit down at the table and argue about this and come out with the best solution. Over here, it's like we are sitting across the table, throwing darts at each other."[31]

Although advisory committees do help regulators access information essential to buttress agency decisions and hence minimizing risks of external political and judicial interference (McCubbins, Noll and Weingast 1987: 257f.; Moffitt 2010: 891), the articulation of partisan interests is not conducive to a reciprocal search for prevention strategies. Cooperation with regulatory authorities remains a precarious gambit, since it can be construed as tacit admission of the validity of opposing views and in many cases will make regulation more likely. Balanced representation allows regulators to 'shop' among different sources of expertise and support for their regulatory proposals, and the unstable and unpredictable coalition patterns inhibit candor in discussion. But even if companies did believe in the 'benign' intentions of their regulatory adversaries, the participation of competing interests, who might seize on and exploit sensitive information, cautions against frank exchanges.

The procedural transparency associated with advisory proceedings further hampers incentives to share information. FACA requires committees to keep detailed minutes of each meeting, including records of participants and accurate descriptions of their discussions (Croley and Funk 1997: 464f.). Any information disclosed, gathered or disseminated in the course of committee deliberations becomes a matter of public record. Since communications among participants are in the public domain, companies face overwhelming incentives to withhold rather than share information. The most valuable discussions among committee members thus often take place in the hallways before or after the formal meetings (Coglianese, Zeckhauser and Parson 2004: 327). Ultimately, attempts to channel deliberations with American companies through existing advisory bodies have proven insufficient to conquer the cause of their discomfort in sharing sensitive information with federal authorities.

[31] Interview, Washington, D.C., April 19, 2012.

Would deliberations under a less formalized and less transparent procedure have induced American companies to share information with federal bureaucrats? Absolutely! Informal discussion among state authorities and industry representatives facilitates information transmission, just as it facilitates gossip in everyday life. Would it have addressed corporate discomfort in disclosing sensitive information and convinced American companies to engage in candid discussions with federal officials? Perhaps – but probably not. The complexities of the American decision-making environment ultimately create few incentives for companies to seek collaborative settlements with the agencies responsible for regulating their conduct. Although deliberative institutions thus might have helped dispel misgivings about agency intentions and designs, they would not have addressed the fundamental roots of corporate discomfort in sharing sensitive information. Because administrative decisions and policies in the United States can be challenged, revised or overturned at other stages of the regulatory process, companies have little reason to believe that bureaucrats will be able to uphold their end of a cooperative arrangement. Advisory bodies did little to change this evaluation, and their impact on business responses remains negligible.

The U.S. nanotech story instead reflects how fragmentation of regulatory powers affords companies generous opportunities to influence regulatory outcomes through indirect means. The UK story of nanotech regulation is in contrast one of the incentives created by powerful state bureaucrats; but it is also one of regular contacts and dialogue among representatives from industry and state authorities channeled through institutions that encourage participants to gather and share information about joint problems, craft agreed solutions and settle disagreements through discussion and negotiation. Because they improve corporate understandings of agency agendas and designs, the extensive reliance on expert bodies and stakeholder fora in the development of UK chemical safety policy thus helps explain why companies entrust information to state bureaucrats with the power to make – and break – cooperative arrangements.

CONCLUDING REMARKS

The notification of nanomaterials has been at the heart of international nanotech debates for the past few years. With the advent of nanotech on the regulatory agenda, authorities in America and Europe initially pinned their hopes on voluntary reporting. Over time and based on scant industry participation, the initial interest in Denmark, the United States and to some extent Germany has been exchanged for a new focus on statutory instruments. Although mandatory

Table 5.1 Drivers of German and Danish Business Responses

	GERMANY	**DENMARK**
Regulatory Strategy	Encourage cooperation	Encourage cooperation
Nature of Advisory Proceedings	Comprehensive industry participation and representation	Limited industry participation and representation
	➢ Federal authorities funnel nanotech debate through advisory committees and stakeholder fora	➢ Nanotech debate structured around infrequent and issue-specific workshops and conferences
	➢ Regular policy deliberations encourage participants to develop a common diagnosis of the challenges created by nanotech, debate the consequences of different decisions, and reach agreed recommendations	➢ State officials, companies and their representatives do not meet on a regular basis to debate scientific developments, analyze the roots of joint problems and craft agreed solutions
	➢ Through regular discussion, companies learn how federal decision-makers understand the evidence for nanotech and how they evaluate the need for new controls	➢ Companies unable to predict how state authorities might react to new information – and whether such a response might consider their views and interests
	➢ Confidence in the designs of federal authorities creates compelling incentives for companies to volunteer information	➢ Uncertainty about the designs of state authorities inhibits incentives to volunteer sensitive information
Bureaucratic Commitments	Credible	Ambiguous
Business Response	Disclosure	Nondisclosure
Outcome	Joint Decisions	Unilateral Regulations
Nature of Industry Influence	Direct	Negligible
Implications for Business Interests	Business predictability Best practice guidelines Stakeholder confidence	New administrative burdens Market uncertainty Risks of backlash

reporting obligations have been considered in all four countries, only Danish companies now have to register their products with state authorities.[32] Some 1000 Danish companies will be

[32] Denmark is not alone in this respect, however. France was the first country to introduce mandatory reporting obligations for manufacturers and users of nanomaterials and authorities in Australia, Belgium, Canada, Italy, Norway, Sweden and a number of other countries have announced similar plans.

affected by the registration obligation – whether or not they import and use nanomaterials (Fischer *et al.* 2012). The outcome of the Danish policy process thus illustrates that acquiescence can prove a costly luxury for an industry. Since however decisions on the direction of Danish nanotech policy were informed by discussions among a closed group of governmental and academic experts, industry representatives were left without a reliable basis to predict how state authorities might react to new information. A cautious stance was in consequence a sensible response to the policy process; and reluctance to volunteer sensitive information to state authorities a strategy to minimize the economic and administrative impacts of decisions over which companies had little influence. Rather than resign to await state initiative, institutionalized deliberations among German companies, their representatives and federal decision-makers have in contrast created ample opportunities to guide the direction of federal nanotech policy. Confident that federal authorities would consider their views – and where possible respect their interests – companies therefore faced compelling incentives to volunteer, rather than withhold information. Variations in the institutions that structure communications among state bureaucrats and industry thus in short account for the diverse responses of German and Danish companies. Table 5.1 summarizes.

The varied responses of Danish and German companies to the regulatory process and its diverging outcome in the two countries meanwhile capture important elements of the conclusions emerging from my account of nanotech regulation in America and Europe. I have made two claims with respect to the regulatory behavior and interests of business: that fear of state intervention need not be the dominant concern or driver of business behavior; and that industries are willing to share information about their operations – even in the absence of structural constraints on state capacities to intervene. Looking to the arguments fielded against a nanoproduct register by industry representatives in Denmark illustrates the first of these claims. Above we noted how the decision was criticized as futile and unreasonably burdensome for industry. Such objections are to be expected: after all, industries are as a rule held to resist decisions and obligations that might translate into increased operating cost, barriers to market entry, and so. To reiterate the observation made by a U.S. industry insider in chapter four: "there is no appetite for [regulation] in industry right now, because less regulation is preferable – it's cheaper!"[33]

[33] Interview, Washington, D.C., April 16, 2012.

But concerns for their competitiveness were not the only or indeed most forceful objections voiced by Danish companies. Industry representatives likewise and urgently warned that a separate reporting requirement for nanomaterials might feed into consumer perceptions of unexplained or general risks inherent to all nanoproducts. By bringing to public notice the possible existence of a risk, even proposed regulations can significantly shake confidence in an industry or the technology underlying its products, processes and operations (Greenwood 1984; Paddock 2010: 183). Public opinion in Denmark is as we will see in the next chapter still favorable to nanotechnologies. But this could quickly change. Mounting public hostility to nanotech could significantly impair the economic prospects of the Danish nanobusiness community, and industry representatives in short feared that the signal value of new 'nano' regulations could contribute to stigmatize the technology in the public eye (Boteju 2012; Telcs 2012; Zeuthen 2012). While the decision to establish a nanoregister ultimately sparked little attention – and has not notably contributed to public awareness of nanotechnologies in Denmark – industry insiders have complained that past adverse and unbalanced media coverage has left a 'residue' in the public mind; and that this residue has served to significantly erode the market potential of nanotechnologies in Denmark.[34]

Above all however industry representatives balked at the market uncertainties created by the decision to establish a nanoregister. Since the register entails a retrospective reporting requirement, manufacturers and importers of nanomaterials would place products on the market not knowing the number and type of products subject to registration, the frequency of registrations, the scope and extent of information required for registrations, the rules governing data access and the protection of confidential business information. Until specific rules are promulgated, companies will in short be unable to predict and plan for their eventual obligations and compliance costs. These objections draw our attention to the value corporate decision-makers attach to a stable business environment. In chapter four, we thus saw how the main benefits secured by American and British companies can be described in terms of the confidence created by a predictable regulatory response to nanomaterials. Similar corporate concerns and preferences permeate my narrative of the German and Danish regulatory processes. German companies for example readily joined the NanoCare project, exactly because it allowed them learn 'what the federal agencies need or what they want to know'[35] – with participation in joint safety ventures and administrative risk assessment procedures in turn presenting opportunities to

[34] Interview, Copenhagen, June 1, 2011.
[35] Interview, Berlin, June 22, 2012.

mold the knowledge and understandings of federal bureaucrats. While Danish companies were unable to fend off the decision to introduce new statutory obligations, their objections echo the arguments advanced by the VCI in the German debate over a nanoregister (VCI 2011).

The German nanotech story however also illustrates that companies may actively seek and promote regulatory outcomes that translate into greater business predictability – even if they result in new controls. Consider the AGS. Beyond advising the Minister of Employment, the AGS also formulates technical rules for hazardous substances (TRGS). While not statutory regulations, these technical rules constitute statutory *guidance* documents, often inspired or supported by practical guidelines published by Länder authorities or the social partners. Application of a TRGS ensures and assumes that an employer meets the requirements of the Hazardous Substance Ordinance. Failure to observe the guidance laid down in such rules can in contrast lead either to regulatory penalties or to legal action against an employer. Employers in short as a BAuA official emphasized tend to view them *as if* they were legally binding.[36] At its meeting in November 2010, the AGS decided to initiate a rule-making procedure for activities involving nanomaterials – based on the guidelines developed by VCI following the joint BAuA-VCI survey (AGS 2011). Initial policy discussions among BAuA and VCI representatives in 2005, supported by the legal mandate of the AGS, are in other words slowly finding their way through the regulatory process.

While thus rejecting mandatory reporting obligations, German companies have not been opposed to any and all regulatory obligations. Rather they have assiduously sought to encourage – and shape – decisions that could ensure a predictable regulatory environment for the development and commercialization of nanomaterials. A federal official observed:

> "[It] is not true that they don't want to have regulation. Especially in a field where you have a lot of uncertainty, companies want to have regulation. [Not that] they want to have strict regulations that forbid them everything. That is not the point. But they want to have rules that can [tell them] what do the agencies want, what expectations do they have, and so on, and so they can align with this, so they won't have problems with their applications and products later on. […] That is the point: We do not want to have products banned afterwards, because we did not know the rules or the agencies did not know what they really wanted."[37]

Regulations may thus increase costs – but they also serve as guidance to expected behavior. In areas of high scientific and legal uncertainty, such as nanotechnologies, industries therefore usually have reasons to welcome regulatory outcomes that can help them navigate an uncertain

[36] Interview, Dortmund, October 11, 2012.
[37] Interview, Berlin, June 22, 2012.

business environment. While regulations may come at a price to flexibility, a stable regulatory environment also promises significant benefits in terms of business predictability and public acceptance of nanotechnologies, which cannot easily be ignored. Again in the words of the U.S. insider, "[Less regulation] is cheaper, but ultimately it is just not very good for the technology."[38]

The coincidence of industry responses in Britain and Germany meanwhile serve to illustrate my second claim. This chapter opened by noting the conundrum created by this coincidence: operating as they do in markedly different political contexts and under distinct economic circumstances, we should have expected companies in the two countries to react differently. The answer to this puzzle is rooted in the existence of a comparable set of institutions governing the formulation and implementation of chemical control policy. As Wyn Grant and colleagues have observed (1988: 307), "in the chemical industry the differences are not as great as a reading of the literature on government-industry relations in [Britain and Germany] might lead one to suppose. In particular, there is a danger of confusing differences of style with differences of substance." While the organizing logic of the British and German political economies differs, the strategic environment for chemical control policy in the two countries is also broadly similar.

Manufacturers and users of chemicals are thus presented with a set of distinct, but comparable risks and opportunities: companies in both countries confront powerful state bureaucrats. Whereas safeguarding their interests requires American companies to keep the executive agencies guessing about the nature of their products and operations, leverage over regulatory decisions in Britain and Germany is in contrast purchased by volunteering such information and making industrial expertise available to the authorities responsible for regulating their conduct. The reliance on expert bodies and stakeholder fora in the development of chemical safety policy on the other hand also helps explain why companies entrust information about their operations to state bureaucrats with the power to make – and break – cooperative arrangements. Membership of such deliberative institutions bolsters corporate confidence that their views and interests will be considered as new issues emerge; and advisory bodies thus buttress the credibility of bureaucratic commitments. British and German companies are in short willing to share information about their operations – even in the absence of significant constraints on state capacities to intervene – because disclosing such information can succeed in convincing state bureaucrats to make decisions that benefit their interests.

[38] Interview, Washington, D.C., April 16, 2012.

CHAPTER SIX

Anticipating the Backlash: Industry Self-Regulation in Britain and Germany

> *Industry can live very well with laws, because then they know exactly what they should be doing. […] But the public would like to have believes or values, for example 'I swear that I won't harm the environment.' That is for us a little bit difficult, because that is nothing we can put in to operations. It is easier to say: 'to not harm the environment you make these five tests on these safety features.' At the moment, we have more of an emotional society than it was 30 years ago, so you need to [not only] comply with something technical or rational, but you have to show your believes and values. […] Products get approved by an authority or not, whatever the values of a company, because you must hand in the data and they look at it and say: 'is it safe or not?' [However] with a value driven environment, that is not really fitting [and] consumers expect something else than very dry safety studies.*
>
> Industry representative[1]

In November 2006, a group of UK companies came together to explore the technical, social and commercial uncertainties of nanotechnologies. Deliberations on good practice and responsible governance concluded in late 2008 with the launch of the Responsible NanoCode. 2008 likewise saw German companies embrace the NanoKommission's 'Five Principles for Responsible Use of Nanomaterials'. While UK and German companies thus have signalled a voluntary commitment to responsible governance, similar talks of self-regulation among industry leaders in the United States and Denmark never surfaced and no comparable initiatives have been undertaken. In this chapter, I investigate the conditions that led UK and German companies, but not their U.S. and Danish competitors, to pursue a course of self-regulation.[2] I contend that the roots of these diverging self-governing strategies lie with the different roles companies have assumed in the

1 Interview, Frankfurt, October 11, 2012.

2 My interest in industry self-regulation is here confined to collective business initiatives and the circumstances that convince companies to band together with the aim of formulating a *common* code of responsible conduct. Following Neil Gunningham and Joseph Rees (1997: 364f.), I therefore define industry self-regulation as "a regulatory process whereby an industry level (as opposed to a governmental or firm-level) organization sets rules and standards (codes of conduct) relating to the conduct of firms in the industry."

regulation of nanotech. This chapter in turn departs from much of the conventional political science wisdom about the motives for and instrumental value of industry self-regulation. Traditional answers to the question, why do industries self-regulate, emphasize either the desire to capture the benefits from collective action or the need to deflect and minimize costs imposed by external stakeholders. While these are usually reasonable explanations for business interests in self-governance, they nonetheless fall short for nanotechnologies. In this chapter, I show how neither the organization of business interests, market developments nor the prospect of new legislative controls can account for the cross-national variation in industry self-regulation.

Instead we must look to the varied industry responses to the regulatory process and the demands placed on corporate decision-makers by the realities of national chemical control regimes. Regulatory policies decided through mutual agreement and joint collaborations imply that state bureaucrats and companies both have a stake in the final outcome; and inevitably that they must share the political risks and responsibilities for such decisions. This is however treacherous terrain for industry: because consumers and other stakeholders do not or cannot distinguish among members of the 'nano' industry, companies will tend to assume a collective identity in the public eye. Adverse information about the products or activities of one company will consequently color perceptions about the entire industry and the technology as a whole. If left undisputed however regulatory and scientific developments could trigger visceral market reactions as happened for the European agri-biotech industry. The predicament facing industry is therefore one of managing stakeholder perceptions of nanotechnology risks and benefits; and codes of responsible conduct can be understood as instruments to reassure stakeholders that regulatory decisions do not reflect the inherent harmful properties of nanotechnologies. Industry self-regulation in short does not intend to *preempt*, but *complement* state intervention.

In pursuing this explanation for self-regulation, the chapter falls in five parts. Sections one through three consider some plausible alternative reasons why companies might have embraced self-governing responsibilities. I show how self-regulation in Britain and Germany owe little to variations in the legislative control strategies of governments on either side of the Atlantic, differences in the risk perceptions and thresholds of Europeans and Americans or the strength of business organization in these four countries. Section four proceeds to offer a (re)interpretation of the instrumental value of codes of responsible conduct. I suggest that industry self-regulation can be understood as an instrument to garner public acceptance of nanotechnologies and market confidence in industry. I further argue that the impetus for companies to self-regulate arises from cooperation with state authorities. Section five demonstrates how the UK and German codes of conduct intends to shelter companies from future nanoscares resulting from 'irrefutable' or

'uncontestable' information about their products and activities – and how self-regulation was a business response that grew from the incentives and constraints embedded in the British and German chemical control regimes.

SHADOW OF THE STATE

Business interest in self-governance often arises from disputes over the necessity and the terms of authoritative state intervention (Streeck and Schmitter 1985: 130f.). The fervor of the nanotech debate over the past decade, combined with the intense attention of elected politicians, suggests that self-regulation was a business responses crafted to fend off new legislative controls. Analyses emphasizing the shadow of hierarchy see incentives for self-governance emerging from the threat – explicit or implicit – of state intervention. State actors may threaten to enact adverse legislation unless companies alter their behavior (Héritier and Lehmkuhl 2008: 2; Halfteck 2006). Since they command greater expertise and technical knowledge about their economic and technological circumstances, self-governance allows companies to formulate less intrusive and more flexible rules (Ogus 1995: 97f.). To the extent that companies value the flexibility and influence associated with formulating industry specific rules and controls higher than presumably more rigorous and intrusive public regulations, a threat of legislation creates strong incentives to self-regulate (Mayntz and Scharpf 1995; Scharpf 1997: 202f.). According to this story, the diverging self-governing responses of companies were dictated by differences in the control strategies of governments in America and Europe. Unlike their American and Danish competitors, UK and German companies were in short willing to self-govern, because their incentives to do so were more desperate.

If this is indeed the reason why UK and German companies self-regulated, they must have felt convinced that new legislative measures were in the works; and that such measure could be starved off by endorsing a code of responsible conduct. We therefore need to know what might have alerted companies to a looming threat of state intervention; that is, we must investigate the legislative plans, designs and ambitions of the British and German governments. Elected politicians communicate their intentions to businesses explicitly through their statements and implicitly through their actions. Short of public commitments to restrict undesired behavior, publication of draft bills (introducing new or reinforcing existing legislation), discussions in parliament about planned legislation or activities necessary to enact legislation (*e.g.* announcing regulatory reviews, data gathering, and convening working groups with a mandate to consider statutory options) certainly should raise red flags (Halfteck 2006: 35-42; Héritier and Eckert

2008: 119). A flurry of such activities and commitments from elected politicians in Britain and Germany could have persuaded companies that state intervention was imminent.

Elected politicians for their part must pay attention to voter opinion. Whether seeking to capitalize on public sentiments or simply concerned for their electoral prospects, mobilization of public opinion can galvanize politicians to push for state intervention. Media coverage or NGO campaigns are common mechanisms, which can mobilize public sentiment and make large numbers of voters aware of the implications of an issue (Culpepper 2011: 6ff.; Porter and Ronit 2006: 48f.). Sustained efforts to mobilize anti-nano sentiments might therefore have created equally compelling reasons for companies to preempt a political response. If we can show that new legislation was indeed on the table or that the media and NGOs vigorously heralded anti-nano messages to UK and German consumers, we would in short have found a plausible answer to why companies in these companies embraced self-regulation.

Does the evidence support the shadow of hierarchy as a plausible explanation for the self-governing response of UK and German companies? In a word – No! Although the frantic pace of the nanotech debate in Britain for instance at first blush might suggest that momentum for an adverse intervention indeed was building, a closer look reveals that governmental decision-makers never harbored designs for new legislation. We encountered the reluctance to impose mandatory reporting requirements on industry in chapter three; and for HM Government, 'getting it right' evidently meant "do not overburden industry with regulation." (HM Government 2005: 1) Since 2004, all recommendations, which would entail new obligations for industry, have been met with quiet indifference or rejection. Treating nanomaterials as 'new' chemicals, as recommended by the Royal Society and the Royal Academy of Engineering, was for example quickly dismissed in favor of a case-by-case assessment of the need for additional testing (HM Government 2005: 14f.; BIS 2010: 44). Conclusions made by an independent review on the need for a long-term integrated regulatory approach (Frater *et al.* 2006: 32), failed to generated an official response.

HM Government instead time and again committed to address potential 'grey zones' through incremental adaptation and adjustment of existing frameworks (HM Government 2005; 2008; 2009). A separate regulator or a new framework for nanotechnologies were briefly discussed within government circles – and swiftly discarded. One Defra official remarked:

> "It has been considered – but never seriously. When we first started working properly at nanotechnology and regulation, we very quickly understood that nanotechnologies can appear in any one of a number of different regulatory framings. There are particular product sectors, where they can appear and there are potential hazards there, so you need to focus your regulatory efforts in those areas, and that is far better

> achieved by individual regulatory frameworks rather than having something overarching, which then runs the risk of throwing out the baby with the bathwater."[3]

With no political appetite for new legislation, HM Government has consistently maintained that existing legislation offer sufficient protection, while enabling prompt action should risks be identified. Absent conclusive evidence of human or environmental hazards, industry was in short given little reason to expect much less fear state intervention.

Scrutiny of governmental plans, publications and statements in the Federal Republic similarly reveals that neither elected politicians nor regulatory decision-makers nurtured designs for new legislative measures. In none of its statements, strategy documents, or appearances before the Bundestag has the Federal Government expressed an interest in new legislation. Written statements instead overflow with confidence that minor adjustments to existing frameworks would suffice to guarantee human health and environmental integrity. Parliamentary motions sponsored by opposition parties to ban or restrict use of nanomaterials have summarily been dismissed with references to a lack of evidence in support of new controls.[4] What doubts corporate decision-makers might have harbored concerning the Federal Government's legislative ambitions for nanotech were swiftly put to rest in 2004 with the BMBF declaring that "no one sees any need to introduce regulations or additional laws covering nanotechnology." (BMBF 2004: 44) The Federal Government has since repeatedly reaffirmed this conclusion (Beyerlein 2006: 545; BMBF 2007; 2011a; Bundesregierung 2007; 2012). An official review – commissioned to assess the adequacy of existing frameworks and consider the need for new controls – for example concluded that the "idea that the state by means of a strict 'command and control' approach can comprehensively intervene in private research and development departments appears – in both a practical and a legal sense – to offer little promise." (Führ *et al.* 2006: 57).

The Federal Government instead committed to pursue harmonized measures through the European Union, emphasizing that possible decisions must be made in concert with European partners. With REACH time and again identified as the appropriate vehicle to regulate nanomaterials (BMBF 2011a: 37; Bundesregierung 2007; 2012), observers have meanwhile described this commitment as a comfortable disguise for the Federal Government's own inability to reach an agreed position on nanotech.[5] With no clear recommendations on new legislation emerging from the NanoKommission, federal decision-makers moreover were not presented with strong stakeholder pressures to reconsider their priorities or agendas. Insisting that possible

3 Interview, London, March 3, 2011.
4 Phone interview, October 30, 2012.
5 Phone interview, October 30, 2012.

legislative measures or amendments be put off as scientific understandings and evidence mature, federal decision-makers have thus given industry representatives little cause for alarm.

Nor has attempts to mobilize voter awareness or anti-nano sentiments in Britain and Germany presented much cause for concern. Demands for mandatory regulations or even a moratorium have been voiced by some within the NGO community. But in contrast to GMOs, neither Germany nor Britain have witnessed sustained anti-nano campaigning. German NGOs participated with other stakeholders in the NanoKommission. Citing a lack of resources, they were however slow to join the federal NanoDialogue and several major groups such as German Greenpeace never did.[6] Representatives from the NGO community have since expressed disappointment in the outcome and impact of the dialogue process;[7] and some skepticism of federal commitments and policies have been voiced. Ultimately, however, neither German nor UK-based NGOs have pursued strategies which could set them apart internationally (Miller and Scrinis 2010: 420-27) – nor have they embraced messages or tactics that resulted in greater social pressures on governmental decision-makers.

Neither has media coverage created urgent concerns for corporate decision-makers. While the UK media was swift to lash on to the nightmarish 'grey goo' scenario heralded by Prince Charles in April 2003, media attention turned sporadic after May. Coverage was largely confined to a few 'elite' papers, such as Financial Times and the Independent, whose outreach are – relatively speaking – limited (Anderson *et al.* 2005). Despite the interest triggered by the 2006 MagicNano incident, it likewise did not significantly alter the tone or scale of media coverage in Germany (Zimmer, Hertel and Böl 2010b: 103); nor did the incident have a lasting impact on consumer or public perceptions of nanotechnologies. Recalls a federal official:

> "We had 80 intoxications during 2 days – which is quite a lot – but it didn't become a scandal. The public wasn't really interested and it's just like another product: something went wrong, okay, and then they fixed the problem, and it is okay. And it was a product which was not really new […] and I think some people thought: 'okay that can happen, but it is a product we know, it is nothing really new. So it was a mistake, an accident, okay.' And that was it. It had nothing to do with nanotechnology and it didn't spread to the nanotechnology debate."[8]

German and UK companies were in short given few reasons to expect that new legislative measures or controls were on the table; nor were they presented with strong signs to indicate a sea change in the legislative aspirations of governmental decision-makers. During interviews,

6 Interview, Berlin, June 22, 2012.
7 Phone interview, October 30, 2012.
8 Interview, Berlin, June 22, 2012.

former participants in the Responsible NanoCode Initiative gave no indication of working under pressure from an impending state intervention. And, while disagreeing about the appropriate governmental response to nanotechnologies, they unanimously agreed that HM Government in their view never considered measures with a similar scope to the NanoCode – a view confirmed by government officials.[9] Participants instead emphasized a desire to target areas that are 'not laid down in regulation' or that 'regulations can never get into.'[10] There is thus ultimately little evidence to suggest that the NanoCode dovetails into a contingent legislative plan. A similar conclusion applies with respect to the NanoKommission's 'Five Principles': interviews with the code's framers unearthed no evidence to suggests that it was motivated by a desire to preempt legislation. From the very beginning of the German nanotech debate, federal decision-makers instead went to great lengths to allay potential corporate concerns, insisting that possible legislative measures or amendments would have to await international efforts to build the necessary evidence and risk management methodologies. What incentives UK and German companies had for self-governance, they in short did not originate with the legislative ambitions of governmental decision-makers.

Looking across the Atlantic corroborates this conclusion: pressures to reform American chemical management laws mounted steadily during the final years of the Bush administration. With the Democratic Party assuming control of both Houses of Congress in 2008, the election of Barack Obama appeared to consolidate the momentum for reform. Within its first year in office, the new administration had secured significant funding increases for the executive agencies and made several high-profile appointments, leading to talks of a 'revival of the fourth branch.' (Judis 2010) The walls might thus appear to have been closing in on the chemical industry. Bush officials had vehemently rejected that new statutes were required to regulate nanotechnologies (Marchant, Sylvester and Abbott 2007: 192), confirming that "[t]he Federal government's current understanding is that existing statutory authorities are adequate to address oversight of nanotechnology and its application." (Marburger and Connaughton 2007: 2) A federal official reflected: "We didn't change the framework for biotechnology. In other words, we shoehorned living organisms into existing frameworks, and it doesn't fit exactly right. But I think nanotechnology is even easier [since] they are still chemical substances, so I don't see us changing the framework at all."[11]

9 Interviews, London March 3, 2011.
10 Interview, Brussels, March 2, 2011.
11 Interview, Washington, D.C., April 19, 2012.

The Obama administration nonetheless entered office with a plan to push TSCA reform through Congress. Early in her tenure, new EPA administrator Lisa Jackson rolled out innovative and aggressive goals for legislative reform of TSCA, arguing

> "[W]e need to review all chemicals against safety standards that are based solely on considerations of risk – not economics or other factors – and we must set these standards at levels that are protective of human health and the environment. […] Manufacturers must develop and submit the hazard, use, and exposure data demonstrating that new and existing chemicals are safe. If industry doesn't provide the information, EPA should have the tools to quickly and efficiently require testing, without the delays and procedural obstacles currently in place." (Jackson 2009)

Jackson concluded by calling on leaders in Congress to accelerate efforts to update and strengthen TSCA. On April 15, 2010, Democratic Senator Frank F. Lautenberg introduced a reform bill, intended to modernize TSCA, which would require manufacturers to demonstrate the safety of their substances. While the bill did not explicitly address nanomaterials, it would empower EPA to consider 'special substance characteristics', including size, shape and surface structure, reactivity, and any other properties that may significantly affect risks. Powers, which would undeniably and adversely have impacted on nanomaterial manufacturers and users.

If fear of state intervention indeed were driving companies to endorse codes of responsible conduct, then the United States after 2008 should have been a more likely candidate than either Britain or Germany. The Obama administration had the political resolve, if not capacity, to push chemical reform through Congress. Ultimately, while broad consensus on the need for TSCA reform has coalesced, prospects dimmed as industry set to work on convincing Congress against reform. In response to strong pushback from the chemical industry, Lautenberg amended his reform bill to improve its chances of passage – to no avail. House hearings and stakeholder discussions were undertaken throughout 2011 – again to no effect. In the closing months of 2011, Lautenberg expressed intentions to bring the bill up for a committee vote in 'the near future.' That was the last word in 2011. Although Lautenberg reintroduced an amended bill in 2012, the buzz on TSCA reform had gone (Bergeson 2012a; 2012b).

An EPA official observed: "The President came in, wanted to do TSCA reform, found out that this Congress doesn't want to work with [him] – and they have had troubles getting some very basic stuff through Congress, much less TSCA reform – so that's where it is: there is not enough support one way or the other."[12] Talk of TSCA reform is almost as old as the statute itself. Caught up in the fallout from health care reform and the aftermath of the 2010 mid-term

[12] Interview, Washington, D.C., April 19, 2012.

elections, chances of TSCA reform are now as remote as ever. Two observers noted: "We have a stalemate essentially between the Republican and the Democratic Party, which prevents anything from being done in the Congress."[13] "The problem is the really hard right-wing ideologues that aren't gonna do anything that lets Congress look like it is doing something, because they don't want the President to win. […] Our Congress isn't moving anything. You could have bill that just said: 'this paper should go through Congress' and that bill wouldn't move."[14]

Increasingly frustrated with the slow pace of reform, state legislatures have instead begun enacting chemical-specific or product-specific measures in record numbers. 28 states considered toxic substance legislation in 2012 – many with explicit provisions for nanomaterials (Bergeson 2012b); yet, like the Lautenberg reform bill, this has not been preceded by designs for self-regulation. During interviews neither industry insiders nor observers could recall any talk of, let alone need for industry to assume greater self-governing responsibilities. Fear of state intervention may in hindsight never have been at the forefront of industry concerns. But if self-regulation intends to preempt statutory regulations, either TSCA reform or state initiatives should at least have sparked some interest in or talk of self-governance – they did not. Where the capacity to enact new controls did exist, Britain and Germany, the political will to legislate was in contrast entirely absent. Unlike the Obama administration, HM Government had no plans for an overhaul of existing legislative frameworks; let alone designs for business to assume greater self-governing responsibilities. A similar observation can be made for the German government.

The 2006 enactment of REACH of course directs our attention to Brussels; but here too we find that the new European chemicals regime has not been preceded by talk of self-regulation. Where finally new specific powers to regulate nanomaterials have been enacted – notably the recast 2009 EU Cosmetics Regulation, the U.S. Food Safety Modernization Act, which 'miraculously' passed Congress in 2011[15] as well as various mandatory reporting schemes in Canada, France and of course Denmark – they have not been anticipated by calls for self-regulation. Again if fear of state intervention were driving companies to endorse codes of responsible conduct, Denmark would have been a more likely candidate for self-regulation. But despite objections from industrial stakeholders, the decision to introduce a Danish nanoregister was not preceded by designs for self-regulations, let alone suggestions for industry to assume greater self-governing responsibilities. To reiterate, then, what incentives UK and German

13 Phone interview, April 3, 2012.
14 Interview, Washington, D.C., April 17, 2012.
15 Phone interview, April 3, 2012.

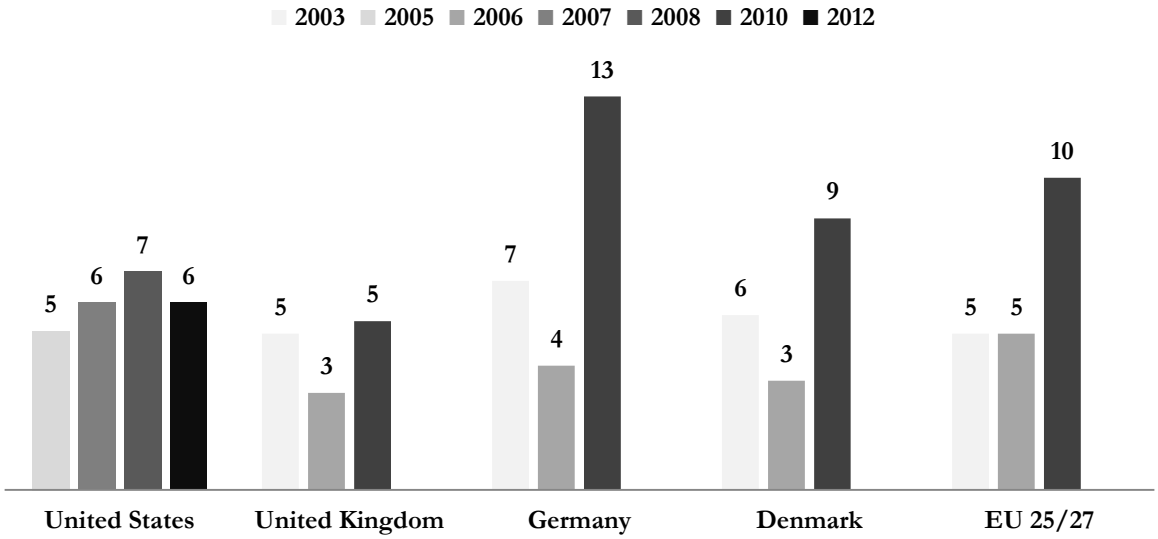
companies had to self-regulate, fear of state intervention has not figured prominently among them.

SHADOWS OF THE PAST

Political imperatives need not be the only source of industry self-regulation. Signals emanating from the marketplace are important drivers of business behavior and voluntary governance mechanisms. Demand-side pressures, channeled through threats of consumer boycotts, 'naming and shaming' campaigns orchestrated by non-commercial third-party, or obligations to business partners, can create equally compelling reasons for companies to embrace self-governing responsibilities (Haufler 2001; Bernstein and Cashore 2007; Vogel 2008). Signs of eroding market confidence in an industry may thus induce companies to band together to formulate codes of conduct with the aim of preempting consumer rejection – or technology stigma. The European GMO experience provides an excellent, if extreme illustration of the implications for industries which disregards such signs: preceding the enactment of new EU labeling requirements in 2003 was a decade fraught with intense policy disputes, vocal opposition from the NGO community, consumer boycotts, and negative media coverage, resulting in deteriorating public acceptance of GMOs in food, suspicion of industry and declining trust in the regulatory authorities charged with overseeing food safety. A perfect storm of anti-GM sentiments, abandonment by business partners, and stringent regulations, culminating in public backlash and technology stigma, significantly impaired the commercial prospects of the European agri-biotech industry.

As another technology with revolutionary promise, nanotech entails all the ingredients for visceral public reactions and market rejection. Self-regulation could therefore be explained as an attempt by industries in Britain and Germany – in the face of mounting opposition – to demonstrate responsible engagement, create public trust and ameliorate corporate reputations, ultimately with the aim of circumventing public fears and 'nanophobia'. Bracketing for the moment the different responses of German and Danish companies, one reading of the Responsible NanoCode might therefore see self-regulation in Britain and its absence in the United States as a result of the diverging fortunes of the American and European agro-biotech industries. Confronted with signs of rapidly deteriorating public acceptance of nanotechnologies, UK companies in this view embraced the NanoCode to forestall escalation of consumer rejection, mistrust of industry and long-term market erosion.

Figure 6.1 Perceptions of Nanotechnology Risks in Europe and the United States



Percentages of respondents answering 'nanotechnology will make things worse' (2003); 'risks [of nanotechnology] will exceed benefits' (2005); 'nanotechnology will deteriorate our way of life' (2006); 'risks [of nanotechnology] will outweigh benefits' (2007; 2008; 2012) and 'nanotechnology will have a negative effect on our way of life in the next 20 years' (2010).

SOURCE: Gaskell, Allum and Stares (2003); Gaskell *et al.* (2006); TNS Opinion & Social (2010); Macoubrie (2005); Hart Research Associates (2007; 2008); Harris Interactive (2012).

This account of the NanoCode presumes two things: first that public opinion in Britain was hostile to nanotechnologies. For obvious reasons, favorable or neutral public opinion would not have swayed corporate decision-makers in favor of self-regulation. Second, hostile public opinion must have been sufficiently pervasive or strident to spark corporate attention and concern. We therefore need to know how public perceptions have developed since polls on attitudes to nanotechnologies began to appear around 2003. Figure 6.1 shows the percentage of respondents in Britain and the United States that reacted pessimistically to nanotechnologies in the period 2003-2012. If fear of consumer reactions explains self-regulation in Britain and its absence in the United States, public confidence in Britain must either have shown signs of rapid decline, been notably more hostile than in America, or both. As we can see from figure 6.1, this is not the case. Although opposition to nanotechnologies is pronounced in neither country, perceptions in the United States have been equally or more negative than in Britain. Survey results released in July 2006 (Gaskell *et al.* 2006) – four month prior to the launch of the Responsible NanoCode Initiative – moreover showed a decline in pessimistic responses and a seven point increase in people reacting favorably (from 24 to 31 percent) – a development explicitly referenced by the

NanoCode's founding partners (Insight Investment, Royal Society and NIA 2006: 2). Based on these figures, U.S. not UK companies should have assumed self-governing responsibilities.

But perhaps this comparison misses the point entirely. Public interest in, awareness of, and opposition to GMOs in the United States has been episodic, rather than sustained. While consumer attitudes toward GMOs did become more negative after the monarch butterfly and StarLink controversies, Americans are not, and never have been, as hostile toward GMOs as their European counterparts (Sylvester, Abbott and Marchant 2009: 168; Vogel 2012). And, unlike European governments, the Federal Government did not take strong regulatory action. Because public opinion in the United States never hardened against GMOs, American companies had little reason to expect or fear a public backlash against nanotechnologies; and they therefore saw no reason to preemptively shore up public confidence by engaging in self-regulation. In Europe, the starkness of the GM debacle painted a very different picture for corporate decision-makers: here public debate about GM foods began just as the BSE food crisis struck – a coincidence, which helped link the two issues before the public. As the epicenter of the BSE crisis, consumer reactions to GMOs in the United Kingdom were especially visceral. The BSE scandal created a 'crisis of confidence' in both science and government and left Britain with a legacy of public suspicion and mistrust in industry and fear of new technologies (Moore 2001: 176).

We could therefore contend that the combined experience of BSE and GMOs has left UK companies more risk adverse – or at the very least more alert – than their U.S. competitors. Although early surveys reported largely positive attitudes, awareness of nanotechnologies also jumped from 29 percent in 2004 to 44 percent in 2006, with 57 percent of respondents unable or unwilling to take a position (BMRB Social Research 2004; Gaskell *et al.* 2006). UK companies may in these figures have found a powerful stimulus for preemptive action. Because so little is still known of the technology's risks and benefits, public perceptions remain volatile. The founding partners thus reasoned that

> "public perception of risks is dynamic and while currently people are broadly well disposed towards nanotechnologies this cannot be counted on indefinitely. […] These perceptual risks depend on the ability of companies and governments to minimise unintended consequences, develop beneficial technologies and adequately govern the exploitation of the technologies (Insight Investment, Royal Society and NIA 2006: 3).

The misfortunes of the European agri-biotech industry in short serve as a cautionary tale and may explain why UK companies – anxious to avoid past mistakes – embraced the NanoCode. To settle this claim, we must look beyond Britain and the United States. Figure 6.1 therefore also includes results from Germany and Denmark, countries equally haunted by public hostility to GMOs. If past experiences explain self-regulation, public perceptions of nanotechnologies

should be similar in Britain and Germany and more negative than in Denmark, where industry did not self-regulate. The latter is indeed the case for Germany, where opposition to nanotechnologies reached close to 13 percent in 2010. But it cannot explain self-regulation in Britain: based on figure 6.1 we would again have expected Danish, not British companies to endorse a code of responsible conduct. Of the countries included in figure 6.1, public opinion in Britain is consistently least pessimistic about nanotechnologies – well below the European average – and hostility is not evidently on the rise.

No clear pattern which could explain self-regulation has emerged from the surveys of public attitudes undertaken to date: perceptions of nanotechnologies are both most and least negative in the two countries, Germany and Britain, where industries have engaged in self-regulation, with opinion in the United States and Denmark nestling in between. It is therefore in short difficult to attribute self-regulation to variations in public perceptions of nanotechnology risks. Although public awareness moreover is growing, studies have tended to demonstrate a positive association between awareness of nanotechnology and the belief that the technology's benefits will outweigh its risks (Cobb and Macoubrie 2004; Gaskell, Allum and Stares 2003; Gaskell *et al.* 2006; TNS Opinion & Social 2010; Macoubrie 2005; Hart Research Associates 2007; 2008; Harris Interactive 2012). The situation is dynamic, of course. A major NGO campaign, feeding on lack of trust and past experience, could push public opinion from its current positive position to one which is fearful and risk averse. But while the founding partners may correctly have anticipated that goodwill cannot be counted on indefinitely, an undeniable 'triggering event' has yet to occur. Awareness of nanotechnologies in these four countries is at best episodic, rather than continuous (Anderson *et al.* 2005; Laing 2006; Kjærgaard 2010; Zimmer, Hertel and Böl 2010b). Above we noted the absence of NGO campaigning or sustained media coverage in Britain and Germany; neither have financial stakeholders and business partners in these countries taken actions suggesting that market pressures for voluntary governance were more acutely felt by UK and German companies than their U.S. and Danish competitors – there is for example no European equivalent to the CNT exclusion policy announced by U.S. Continental Western Group in 2008.

THE STRENGTH OF BUSINESS ORGANIZATION

Demand-side pressures thus cannot account for self-regulation in Britain and Germany; but perhaps drivers on the supply-side can. Business interests in self-regulation often result from a desire to improve market coordination and economic efficiency. Market imperfections can create compelling economic incentives to implement common standards that allow companies to

coordinate their behavior, reduce transaction costs and address barriers to innovation and trade (Büthe and Mattli 2010: 444ff.). Common standards and guidance documents for example serve to establish procedures for workplace safety or facilitate effective communications among manufacturers and their customers on quality and safety issues. Voluntary guidelines can further help clarify regulatory obligations and aspects of good product stewardship and they are thus used to complement formal statutory regulations.

Powerful business organizations are often instrumental in formulating and disseminating common technical standards and guidelines on recommended behavior among members of an industry (Hall and Soskice 2001; Knill and Lehmkuhl 2002). Throughout chapters three and five, I have alluded to the central role of the powerful association of the German chemical industry – the VCI. In chapter three, we for example saw how collaboration among VCI and BAuA resulted in the publication of guidance for workplace handling and use of nanomaterials (BAuA and VCI 2007); and the VCI has since issued various other guidance documents and recommendation papers to establish best practices for the responsible production and use of nanomaterials. Examples include guidance to implement Responsible Care for nanomaterials, assist members with regulatory compliance, enable effective communication among member companies and their customers in the value chain, and the management of health, safety and environmental aspects of nanomaterials throughout their life cycle (VCI 2008). The NanoKommission's Five Principles likewise intend to provide guidance for companies on responsible governance and best practice, and perhaps they are therefore best understood as an expression of VCI's commitment to support the operations of its members. In this view, the reason German companies embraced self-governing responsibilities was to resolve coordination problems resulting from a mix of scientific, technical and regulatory uncertainties. With their powerful association acting as catalyst of agreement, German companies were in other words able to implement common standards of best practice intended to foster market efficiency, reduce transaction costs and address barriers to innovation.

If the strength of their association did indeed enable German companies to self-regulate, we can expect that the association of UK companies, the Nanotechnology Industries Association, displays features or characteristics comparable to those of the VCI. If powerful business organizations in other words explain why some industries embrace self-governing responsibilities, while others do not, then the NIA together with the VCI must belong to the group of powerful associations. What do we mean when we speak of powerful business organizations? What makes VCI powerful? There are many answers to this question. We might for example refer to the political influence which flow from the economic weight of the German chemical industry. Or

we might refer to the VCI's capacity to coordinate the strategies and activities of its members. We might also refer to its control over organizational resources and its autonomy to select associational goals and the strategies it believes necessary to achieve those objectives (Schmitter and Streeck 1999). Or we might refer to all of those things. If the Five Principles are indeed an instrument to guide and coordinate the operations of members, we must examine what enables the VCI to formulate and disseminate such common standards. A representative described the process like this:

> "What is normally done in VCI, and maybe in all associations, it's typically the big companies who write guidance for the small ones. The big ones can also better analyze the law, what it means, and so on, and then it is shared. […] In a lot of cases, the best practice is always starting in big companies, because they always have the lowest level of workplace accidents – in any field. This means they do something right. […] Normally, the best practice in health and safety is established in big companies and then through associations transferred to the small companies."[16]

Exchange of information is the most obvious and basic function of any business association. Members benefit from information exchanged through their association as it for example reduces individual costs of gathering information on markets, competitors or best practices. Information shared through their association can in turn induce members to adjust their business strategies and activities. Information circulated among members and between members and their association can in other words result in coordination of behavior (Culpepper 2003: 99; Schaede 2000: 43). The more extensive, accurate and regular information members receive from their association, the more it will impact on their behavior. Associations which can routinely draw, process, and diffuse information from and to a wide member base are thus better able to coordinate the behavior of members.

Herein lies perhaps the most basic source of strength for the VCI. VCI represents the interests of more than 90 percent of the enterprises operating in the German chemical industry. With a near monopoly on representation, there is no significant branch or sector association organized outside the VCI (Grote and Schneider 2006: 129). The encompassing membership implies that the VCI is able to obtain information on and from companies operating in all areas of the German chemical sector; and in turn diffuse information back down to companies situated across the entire supply chain. A representative remarked: "If you are under one roof [of course] you talk better."[17] By providing information on how their competitors organize and manage their operations, the VCI plays an important role in establishing common standards among German

[16] Interview, Frankfurt, October 11, 2012.
[17] Interview, Frankfurt, October 11, 2012.

companies. Knowledge and information about their rivals shared through the VCI help members adjust their business strategies; and information collected and disseminated by the VCI on how their competitors are reacting to associational guidelines in turn creates further incentives for members to adopt and converge around common standards. The capacity to collect, process and circulate information on and to members operating across the entire chemical sector in short induces and enables companies to coordinate their behavior. In this very fundamental sense, then, the strength of their association is based on the degree of organization among German companies.

By this metric, it is immediately clear however that the VCI is an altogether different associational 'beast' than the NIA. The NIA represents the interests of a mere 23 members hailing from a wide range of application areas and product sectors. While the small membership do facilitate information exchange among members and between members and their association (Schaede 2000: 30f.),[18] it also restricts the extent and completeness of information the association can circulate to members. The NIA in other words has only limited capabilities to coordinate the behavior of its members. There are three reasons for this: First, the NIA represent some of the most prominent nano companies, such as *e.g.* BASF and L'Oreal. These 'industry champions' might of course help establish and supply norms and standards that could be share through the association. Since the NIA organizes few small or medium sized enterprises relative to the number of large companies, there is however little immediate demand for such best practice guidelines. Other multinationals can establish their own guidelines and thus have limited need for the association to formulate and circulate best practice documents; and they might instead prefer that the association direct attention towards objectives that better serve their interests. Unable to sway associational policies and priorities, smaller members are in effect forced to look for guidance beyond their association.

Second, the heterogeneity of its membership further limits demands for the association to identify and formulate common guidelines. Best practice developed by a company specializing in say material science need not be directly applicable to those targeting medical applications; and there is thus little need to share such information and experiences through the association. Common standards and guidance documents are finally in important ways comparable to language groups: the benefits from learning a given language are proportional to the number of people who speak it (Prakash and Potoski 2007: 783). The benefits of common standards are

[18] Interview, Brussels, March 2, 2011.

similarly related to the number of companies that adopt them. While standards and recommendations formulated by the NIA might serve to guide the operations of its 23 members, their impact on competitors would likely be limited. Given its small membership, the NIA is unable to promote the adoption of associational guidelines across the industrial supply chain; nor is the association able to routinely obtain and provide accurate information on how nonmembers are reacting to associational guidelines. Members therefore have little reason to expect that industry norms will converge on standards formulated by their association. Since the NIA plays no prominent role in establishing common industry standards, members have few incentives to use the association to coordinate their commercial and risk management practices. The NIA instead remains first and foremost a vehicle to voice the political views and demands of its members; and beyond the Responsible NanoCode, the association has published no documents intended to establish guidance or standards for companies commercializing nanotechnologies. While the NIA and the VCI both exist to serve the interests of the members, as business organizations go, the two associations are about as different as they come.

The strength of organization is thus not a good predictor for codes of responsible conduct. Degree of organization is of course not the only source of power for business associations. Regardless of how we might think of powerful business organizations, there can however be no question that the American Chemistry Council, the UK Chemical Industries Association or the Confederation of Danish Industry are leagues apart from the NIA. Yet, none of these associations have endorsed codes of responsible conduct. If it was indeed the strength of their association that enables companies to self-regulate through agreed standards and guidelines, we are in the curious situation that both the most and the least powerful association in my sample succeeded in doing so. It is thus unlikely that the story of nanotechnologies and industry self-regulation reflect attempts by powerful business associations to implement common standards of best practice intended to improve coordination among their members. It is as I explain next instead the story of the incentives and constraints created by the institutions that underpin relations among state bureaucrats and industry.

MANAGING PERCEPTIONS OF NANOTECH RISKS AND BENEFITS

To understand why companies in UK and Germany self-regulated, we must first consider the risks of market rejection, public backlash and technology stigma. And how codes of responsible conduct reflect a business response intended to mitigate such risks. Debate on nanotech commenced in the immediate wake of the GM Controversy, and the misfortune – and mistakes –

of the European agri-biotech industry as I observed above quickly came to constitute a cautionary tale for the nanobusiness community. To survive and prosper, industries need to ensure stakeholder confidence in the activities of their members and acceptance of the technologies underlying their products and processes. Failure to heed signs of declining trust or backlash can result in significant economic or reputational costs for industries in ways that could threaten their commercial prospects and long-term legitimacy. If the public turns against an industry, financial stakeholders, business partners and politicians are sure to follow. Should adverse information for example spark public hostility against an industry, politicians may feel compelled to entrench 'irrational' or 'uninformed' sentiment into official policy, cut public funding or erect costly test barriers (Sylvester, Abbott and Marchant 2009: 169). This would indeed be one reading of the GM Controversy – a looming fate that industry leaders clearly have no desire to share. If nanotech is to avoid the fate of GM, stakeholders – business partners, investors, insurers, employees, the media, and especially customers and the public – need to be reassured that companies commercializing nanotechnologies are proactively and effectively mitigating any risks related to them. The commercial viability of the nanobusiness community in short hinges upon the ability to garner public acceptance of the technology as well as market confidence in industry.

The 'nano' industry, of course, is a fiction. While we can identify a (small) core population of companies, where the nanotech aspect is dominant, the vast majority of research and development is undertaken within established and very different industries and market sectors. The sheer number of facilities, combined with the heterogeneity of research and production processes, denies all but a small number of specialists a clear understanding of the industry. Given this complexity, stakeholders not least the public naturally struggle to distinguish among members of the industry. Assessing the performance and characteristics of individual companies requires massive amounts of information; a daunting and elusive task even for more resourceful stakeholders, such as regulators or financial analysts. Consider, for example, the implications of a safety study linking a specific company's nanomaterial, say multi-walled carbon nanotubes, to cancer. Markets and regulators will certainly take steps to penalize the 'culpable' company, *e.g.* through restrictions on use or depreciating share prices. But what of the implications for other companies involved with similar materials or even nanotechnology in general? Few consumers will probably pause to contemplate the differences between single-, double- or multi-walled carbon nanotubes and less so their various toxicological properties. Rather, consumers may quickly jump to the straightforward, but incorrect conclusion that all nanoproducts cause cancer. Even more sophisticated observers, like regulators, insurers or financial traders, may however be

susceptible to grouping carbon nanotube producers and users together. Public, commercial and regulatory reactions might thus reverberate throughout the wider nanobusiness community. Although the study in question was undertaken for a single company's specific nanomaterial, the evaluation of the results will, albeit to varying degrees, color judgments about the entire industry.

Because stakeholders do not or cannot relate information to each individual member of the industry, 'nano' companies – whether they hail from the chemical or other industries – tend to share a common stakeholder assessment of their character and relative performance. As information about the activities of one company or group of companies become available, it will to some degree affect the evaluation of the entire industry (Nash 2002: 239). An error attributable to a single company – whether this consists of an accidental release of toxic nanomaterials, a product recall or a negative toxicity finding – might in other words cause very real harms for its competitors. Research in financial economics has quantified the implications of such spillover harms: Gregg Jarrell and Sam Peltzman (1985) for example found that a drug recall by one pharmaceutical company caused the stock portfolio of 50 rival companies to drop by one percent. Even stronger effects were demonstrated for other industries, such as the automobile industry. Information asymmetries among companies and their stakeholders in other words intertwine the fates of members of an industry.

Since 'nano' companies assume a collective identity in the public's mind, members of the industry share a pooled risk of stakeholder sanctions (Barnett and King 2008: 1150).[19] The now infamous MagicNano debacle, which propelled nanotech into the world's media spotlight, gave nano companies a first taste of "the palpable exposure of an entire industry being [mis]judged on this single misunderstanding." (Bowman and Hodge 2008: 481) While public opinion still is favorable to nanotechnologies, stakeholder perceptions are – because so little is still known of the technology's risks and benefits – volatile and subject to rapid change. The pervasive uncertainties about the technology's future trajectory, its unknown risks and the (slowly) evolving regulatory environment imply that even seemingly innocent information can have major impacts on stakeholder perceptions. As they learn about the technology and the industry, stakeholders adjust and update their perceptions about the safety and commercial prospect of nanotechnologies. With every industrial accident, product incident and negative toxicity finding, companies therefore slowly chip away at favorable stakeholder perceptions. As adverse information

[19] Such interdependencies can of course have positive effects. The high-tech 'nanolabel' may constitute an intangible asset that helps companies attract private and public funding, develop competitive advantages, and ultimately drive long-term profitability. Interdependencies can thus be favorable if, for example, one company's success helps to legitimize the emerging industry and so eases all companies' access to resources.

accumulates, it could precipitate a tipping point, triggering widespread backlash, stigma or even nanophobia. Even a single event – possible evidence of harm, a product recall or restrictions on use – could do irreparable damages to consumer confidence, causing long-term erosion of the market potential of nanotechnologies. Regrettably, for industry however, news of accidents, incidents and safety concerns *will* continue to surface, if not for other reasons then simply because of the sheer number of companies involved, the projected future pervasiveness of nanotechnologies and because some nanomaterials, like their bulk forms, are (very) toxic. A nanoscare is therefore not an implausible future outcome – it is in fact bound to occur. This is where codes of responsible conduct enter the frame.

If 'bad news' engender backlash, anticipating such information will also be an essential element of the solution (King, Lenox and Barnett 2002: 403). Turn to the blunders of the biotech industry: proponents mistakenly assumed that rational arguments could effectively influence the response to biotechnology. While markets and consumers did indeed recognize the benefits of biotechnology, fear of potential abuses and accidents ultimately captivated public imaginations. Proponents of biotechnology continued to raise rational arguments in defense of the technology, largely dismissing the risks as exaggerated. Unfortunately, for proponents, to no avail (Matsuura 2004: 492). As Paul Slovic (1987) explains, risk perceptions are systematically linked to the characteristics of the risk: an accident that claims many lives may produce relatively little disturbance, if it occurs under familiar and well-understood circumstances – train-wrecks provide an oft cited example. Even a minor accident "in an unfamiliar system (or one poorly understood) may [however] have immense social consequences if it is perceived as a harbinger of further and possibly catastrophic mishaps." (Slovic 1987: 284) Stakeholder reactions will be stronger, where the risk in question is perceived to be involuntary, uncontrollable or invisible, has a delayed or irreversible effect, is memorable, very uncertain, poorly understood, unfamiliar, and unfairly distributed – all elements which characterize nanotechnologies. Because the risks of nanotechnologies are (perceived as) unknown and potentially catastrophic, accidents will be highly publicized and may produce large ripple effects. Even relatively unremarkable incidents could therefore conjure up images of "a sinister technology run amok." (Economist 2006)

The predicament facing industry is in short one of managing stakeholder perceptions of nanotechnology risks and benefits; and codes of responsible conduct can be understood as instruments to familiarize stakeholders with important attributes and characteristics of the industry and the technology. Michael Barnett and Andrew King (2008: 1155) explain:

> "From the perspective of information economics, if a stakeholder already understands the propensity for an error, the occurrence of an error should provide no new information. From a psychological perspective, information provided in advance of an error may also influence how the error is interpreted

> by reducing the degree to which stakeholders view any observed error as informative about unobserved dangers, thus resulting in a soothing effect."

A code of conduct may reduce the harmful effects of interdependencies by communicating information about members of the industry and the technology itself, such that future bad news is viewed to reveal little or no new information of relevance and so have limited impacts on perceptions of the safety and commercial prospect of nanotechnologies. Michael Barnett (2007) for example reports how voluntary codes can influence stakeholder evaluations of an entire industry. John Peloza (2006) similarly argue that voluntary governance measures can mitigate risks arising from negative events that would otherwise harm corporate financial performance: being trusted by stakeholders reduces financial risks arising from safety issues, potential boycotts and loss of corporate reputation. In codes of responsible conduct, companies may thus see instruments to reassure their stakeholders that they understand the technology and are proactively and effectively mitigating any potential risks. Self-regulation may in other words serve to shelter the industry from criticism and hysteria in the wake of a future nanoscare: to the extent that incidents or accidents can be written off as caused by a few 'bad apples' or a series of unfortunate, but otherwise manageable circumstances, companies can garner public and market confidence that industry at large is taking a responsible approach to development.

But insofar backlash is a shared risk of all companies, it has yet to precipitate a universal drive to self-regulate among national industries; and none of the above tell us why UK and German companies self-regulated, while their American and Danish competitors did not. The answer I argue lie with how regulation can impact on stakeholder perceptions and the varied roles companies have assumed in the regulation of nanotech. There never was any solid scientific evidence that GMOs pose serious dangers to health or safety (Sylvester, Abbott and Marchant 2009: 169); but the absence of scientific evidence did not prevent a statutory response. Initial regulatory decisions, negotiated by EU governments in the 1980s, came quickly to represent more than merely the statutory basis for evaluation of specific GM products. As Matthew Kernes and colleagues (2006: 294f.) note: "[Directive 1990/20] acted to constitute a *normative* framing that structured how the *nature* of GM artifacts was understood by the policy community *and* the way that possible impacts ('to human health or the environment') were conceptualized and analysed in wider media and NGO discussion." (*Emphasis in original*) Much of the subsequent anti-GM sentiments thus originated with initial decisions governing the technology and its products (Bernauer and Meins 2003).

Regulation as I have observed not only increase operational costs and punish wrongdoing. They also help build – or break – confidence in an industry. The absence of a clear regulatory response to nanotechnologies readily feeds into perceptions of government inaction in the face

of unknown hazards and thus risks enabling a perception of the Wild West, with companies playing fast and loose with human health and environmental safety (Seear, Petersen and Bowman 2009: 75). This is unmistakably treacherous terrain for industry. More dangerous still is however the signal value inherent in any new 'nano' legislation or 'nano' regulations. A German official observed:

> "A nanotechnology law would be perceived as a problem: you only regulate something which is a problem. Regulations are always an answer to a problem. That would have been something where the public would have said: 'We have a nuclear power law and GMO law. Why do we need a 'nano' regulation?'"[20]

By bringing to public notice the possible existence of a risk, even proposed regulations can significantly shake confidence in an industry (Greenwood 1984: 87). Consider the experience of agrichemical giant, Monsanto. In 1984, U.S. EPA was moving aggressively against one of Monsanto's top pesticides, alachlor. When a trade newsletter reported that EPA was considering an emergency ban, followed by cancellation of all alachlor registrations, a Wall Street analyst down-graded his rating of Monsanto's stock. In short order, the company's share price fell so rapidly that the New York Stock Exchange briefly suspended trading of Monsanto stock. EPA, under pressure from Congress, never promulgated a ban of alachlor (Fagin, Lavelle and the Center for Public Integrity 1996: 83ff.). But the incident does illustrate the vulnerability of even corporate heavyweights like Monsanto to rumors of regulation. For most multinationals, nanomaterials of course still constitute a minor part of their business. But as they tie their futures to nanomaterials, large chemical manufacturers might increasingly find their exposure to information emerging from the regulatory process alarming. For SMEs and start-ups, however, whose business model is entirely focused on nanotech, reports of 'nano' regulations could prove disastrous.

Short of a major accident, unequivocally unmasking the sinister side of nanotechnologies, the primary source of bad news for industry is in short the evolving regulatory process. Given the volatility of stakeholder perceptions, even unremarkable events, ambiguous safety results or routine regulatory decisions, could impact significantly on the perceived risks of nanotechnologies. Uncertainty about how to extrapolate evidence that a substance causes cancer in laboratory animals to humans is for example unlikely to substantially diminish the adverse publicity associated with the discovery of its harmful effects (Wagner 2004: 1634ff.). To avoid widespread consumer rejection, preempt backlash and mitigate spillover harms, companies in

[20] Interview, Berlin, June 22, 2012.

other words need tactics to deflect and anticipate adverse information. Yet the options and tools available to companies that cooperate with state authorities are very different from those available to companies that do not.

Cooperation and agreement among state bureaucrats and companies imply that both parties have a stake in the final outcome; and inevitably that they must share the political risks and responsibilities for such decisions. Where influence however is purchased through access to state authorities, companies must also be cautious of strategies that could be viewed as disruptive to ongoing relationships – and this would include avoiding tactics intended to weaken the legitimacy of regulatory decisions. Under these circumstances, industry is 'locked' into the joint scientific and regulatory outcomes of cooperation. But herein lies the danger for industry: if left undisputed regulatory and scientific developments could trigger strong market reactions against individual companies or the entire industry. Yet, if companies must support – or at least refrain from challenging – regulatory decisions to maintain their access and influence with regulators, they need an alternative instrument to manage stakeholder perceptions. And this is what creates the impetus for codes of responsible conduct. Bound by the contingencies of cooperation, codes of responsible conduct may shelter industries from future nanoscares by reassuring stakeholders that scientific results and regulatory decisions do not reflect the inherent harmful properties of nanotechnologies. Companies reluctant to cooperate with state bureaucrats in contrast have no responsibility for regulatory decisions or government-sponsored safety studies; and they can therefore say what they please about them. Companies resolved to denounce their regulatory adversaries usually find ways to contest scientific conclusions and dispute regulatory actions – and such tactics could certainly also be employed in the court of public opinion to communicate safety results and frame regulatory developments – and they will consequently have little need for self-regulation as an instrument to manage stakeholder perceptions.

RESPONSIBLE NANOTECH: INDUSTRY SELF-REGULATION IN BRITAIN AND GERMANY

The NanoKommission concluded its first phase by endorsing 'Five Principles for Responsible Use of Nanomaterials' (Catenhusen and Grobe 2008). Drawn up and inspired by deliberations among members of Working Group 3, the Five Principles reflect a multi-stakeholder consensus on principles and guidelines for responsible governance within the chemical industry. With an explicit ambition of complementing existing regulatory mechanisms, the principles are intended to assist companies in the interim period as legislative frameworks are being evaluated and updated (Catenhusen and Grobe 2008: 52; NanoKommission 2008a). While participants were

unable to agree measures to monitor implementation or clarify the extend of binding commitments – questions deferred to the NanoKommission's second phase – the principles summarize those issues on which representatives from federal authorities, industry and other stakeholder groups could reach consensus on recommendations for practical guidance.[21]

In Britain, the launch of the Responsible NanoCode in late 2008 signaled a comparable commitment to responsible governance of nanotechnologies. Developed by a process of multi-stakeholder engagement, the NanoCode aims to establish consensus on good practice, while promoting "transparency and accountability and so help build confidence in the technology to ensure its potential is also fulfilled." (Insight Investment *et al.* 2008: 5) Born of a corporate desire to avoid 'another GM',[22] interviews with former participants confirmed the need for companies to understand and respond to the concerns of their stakeholders. One participant recalled: "the businesses asked for help on communication. They felt the problem was: 'we don't know how to effectively communicate with our stakeholders.'"[23] A NIA representative noted: "We felt that it would be appropriate both of informing our members where responsible development needed to be set and where it needed to be agreed on as a guidance to members, but also to provide to the outside a transparent display of how responsible the nanotechnology industries were."[24]

A similar observation can be made for the Five Principles. Explains an observer:

> "[The companies] were afraid of the GMO debate and they are still afraid of the it! […] So they did everything to avoid regulation and that was also why they were involved in the NanoDialogue and why they had these [Principles] developed, because the idea behind this was to have criteria industry would apply to and to have something where you could say: if you don't stick to these criteria then you will have a nanotechnology law."[25]

A federal official elaborated:

> "There was no fear of nano, but they wanted to prevent fear. [The rationale was] we don't know how dangerous nanomaterials are – this is often the problem when you have new technologies – but we are sure that we can deal with it – that German industry is responsible enough to do it and that German industry has the technology to deal with it. And they said: 'how can we bring this to the people? How can we make sure it works?' And then there was this idea to put out these principles, so companies can say that they will comply with these principles as a voluntary statement, which is better than to have nothing. It was too early for regulation […] The idea was to have no regulation, but to have this voluntary standard to say: 'we are complying to a standard.' So [consumers] can say 'then it is okay for me.' […] That was the

21 Interview, Berlin, June 22, 2012.
22 Interview, London, June 8, 2011.
23 Phone interview, March 1, 2011.
24 Interview, Brussels, March 2, 2011.
25 Interview, Berlin, June 22, 2012.

> idea of the [principles]: to put this process in a way that everyone says: 'OK, even if I personally – like most of the people here in Germany – are not familiar with these problems, I have trust in that everyone who is dealing with it does his best and takes efforts and looks for our safety.'"[26]

In both countries, business interests in self-regulation grew from the need to garner public acceptance of nanotechnologies and market confidence in industry. Endorsing a code of responsible conduct thus assists companies reassure their stakeholders that they are proactively and effectively mitigating possible risks related to their activities.

We here arrive at a second point of tangency between the Five Principles and the Responsible NanoCode: their lack of binding commitments. Neither the British nor the German code confer obligations on participating companies. The codes are instead meant only to provide companies with guidance on responsible governance and suggestions of good practices during the transitional period in which regulatory frameworks are developed. The NanoCode for example merely intends to "assist with the evolution of such legislation by clarifying the principles which may underpin more detailed, verifiable, standards." (Insight Investment *et al.* 2007: 1) A UK official remarked:

> "The [NanoCode] doesn't have any regulatory significance. It doesn't confer anything. But it does indicate a company takes seriously the need to make sure their products are safe and make sure their processes don't present hazards to human health and the environment. So, yeah, I think it goes hand in hand really. It's not a part of regulation [but] it's certainly something we are happy to stand behind, happy to see a code developed."[27]

Much to the disappointment and frustration of some participants (Grobe 2011; NanoKommission 2010b),[28] a similar conclusion applies to the German code of conduct. The Five Principles represent a direct result of discussions among industry and governmental representatives. But while the principles thus are intrinsically linked to the regulatory process – they are not themselves binding. An industry participant offered this view:

> "Most of the Principles can be found in the first article of the laws governing us […] For example, we protect the workers – which is one Principle – it is in Article One of the Worker Safety Law in Germany. […] The chemical industry is so heavily regulated that the only principle which goes beyond the legal requirements is the Principle of communicating with the community. Everything else you can find nearly word by word in the very first article of the law."[29]

By communicating information about members of the industry and the technology, the NanoCode and the Five Principles intends to shape and manage the perceived risks and benefits

[26] Interview, Dortmund, October 11, 2012.
[27] Interview, London, March 3, 2011.
[28] Phone interview, October 30, 2012.
[29] Interview, Frankfurt, October 11, 2012.

of nanotechnologies, and the two codes can thus help companies anticipate adverse information about their products and activities: should the codes in other words succeed in familiarizing stakeholders with the industry and the technology, future 'bad' news may be viewed to reveal little or no new information of relevance and hence have limited impacts on perceptions of nanotechnologies. British and German companies in short embraced self-governing responsibilities as a strategy to shelter their operations from future nanoscares.

Self-regulation was in turn a business response that grew from the incentives and constraints embedded in the British and German chemical control regimes. While the desire to avoid market rejection obviously applies to all nanobusinesses, cooperation among state authorities and industry in Britain and Germany entailed its own dangers of backlash; and conditioned a search for tools to deflect and anticipate adverse information resulting from joint safety studies and agreed regulatory outcomes. We can gain an intuitive grasp of how the strategic environment for chemical control policy commands the choice of tactics intended to communicate safety results and frame regulatory decisions by contrasting corporate risk-benefit calculations in the United States and Britain.

Because they have been reluctant to cooperate with federal decision-makers, American companies have no direct stake in regulatory decisions: since they do not participate directly in drafting regulatory proposals, they have no direct influence or responsibility for their content; and they can therefore say what they please about them. While new 'nano' regulations of course do risk inciting consumer fears, driving financial stakeholders away, adversarial sound and fury is also well-suited to paint persuasive pictures of bureaucratic excess, caprice or incompetence (Badaracco 1985: 143f.). The very same tactics used to contest, refuse and obstruct regulatory action can be employed in the court of public opinion to communicate scientific results and frame regulatory developments. By retaining their independence and formal distance from regulators, American companies are thus not only able to exercise significant, but indirect influence on the direction of U.S. nanotech policies; they will – in the short to medium term at least – in their delay tactics also find the instrument to shape stakeholder perceptions of nanotechnologies.

UK companies in contrast find themselves in a more precarious situation. Since influence in the British regulatory system hinges upon access to the executive, companies must be cautious of strategies which could jeopardize that access – and this would include avoiding tactics intended to weaken the legitimacy of joint safety studies and agreed decisions (Grant 2001: 343). Business in Britain of course does not shy away from criticizing governmental policies it finds objectionable – chemical control policy is no exception. The situation is different, however, where regulatory

policies are the outcome of mutual agreement or joint collaborations among industry and regulators. Cooperation and agreement among state bureaucrats and companies imply that both parties have a stake in the final outcome; and inevitably that they must share the political risks of such decisions. Since moreover British regulators are largely free to structure and manage access to administrative proceedings, companies must be wary of strategies which could be viewed as disruptive to ongoing relationship, as failure to observe tacit accords ultimately risks exclusion (Grant 2004: 408f.). The realities of the British regulatory system in short 'locks' industry into the joint scientific and regulatory outcomes of cooperation.

But herein lies the danger for UK companies: if left undisputed regulatory and scientific developments could trigger visceral market reactions against individual companies or the entire industry. Confronted with adverse findings from a joint safety study on say nanotubes, corporate sponsors will inspire little confidence in their products by admitting: 'Yes, nanotubes may cause cancer, but not *our* kind of nanotubes.' Given the volatility of stakeholder perceptions, failure to dispute safety findings and regulatory developments could do irreparable damages to consumer confidence, causing long-term erosion of the market potential of nanotechnologies in Britain – as happened with GMOs in the wake of the BSE scandal. Yet, if companies must support – or at least refrain from challenging – the results of collaboration to maintain their influence with regulators, they need an alternative instrument to manage stakeholder perceptions – to reassure stakeholders that regulatory decisions do not reflect the inherent harmful properties of nanotechnologies – and that instrument was the Responsible NanoCode.

In Germany, self-regulation likewise reflects the need for companies to divert the harmful effects of future nanoscares resulting from 'irrefutable' or 'uncontestable' news about their products and activities. Unlike Britain, regular cooperation with named interest groups is a requirement of many areas of German toxic substance legislation – and the *de facto* discretion of federal authorities to manage and structure access is limited. Although the bounds of cooperation in consequence are less pronounced for German companies, they too confront compelling reasons to endorse agreed outcomes. While German toxic substance legislation guarantees access for industry views and hence locks regulators and companies in an ongoing relationship, it need not necessarily be maintained on congenial terms. Cooperation is as I have observed a desirable, but not inevitable feature of chemical control policy – conflicts, suspicion or even antagonism among companies and regulators are not uncommon. For companies, the mere existence of a relationship is thus trivial. What matters is the terms and results of that relationship (Scharpf 1990; 1994: 43f.). Bureaucracies develop institutional memories over time and companies willing to jeopardize the terms of their relations with state bureaucrats by publicly denouncing agreed

decisions must anticipate a frosty welcome in future dealings (Wilson 1989; Badaracco 1985). Although federal authorities are unable to exclude belligerent industry representatives, they certainly have ways to make life more difficult for them. Simply failing to return a phone call or to invite industry representatives to important meetings are common and cheap ways through which regulators can punish uncooperative regulatees (Coglianese, Zeckhauser and Parson 2004: 330).

Because the German chemical control regime places a premium on cooperation, corporate interests are better served by maintaining relations on congenial terms. German companies no less than their UK competitors therefore observe the accords of cooperation; and this entails assuming responsibility for regulatory policies decided through mutual agreement and joint collaborations. We can elaborate this conclusion by briefly looking to the tactics adopted by Danish companies in response to the decision to establish a nanoproduct register. In chapter five, we observed how industry representatives urgently warned that a separate reporting requirement for nanomaterials might feed into consumer perceptions of unexplained or general risks inherent to all nanoproducts and thus contribute to stigmatize nanotech in the public eye (Boteju 2012; Telcs 2012; Zeuthen 2012). Rather than wager that the decision might fail to impact on public perceptions of nanotechnologies, industry representatives instead used the media to criticize the basis for MST's decision and denounce a nanoregister as futile, counterproductive and ultimately harmful to the Danish economy (see *e.g.* Zeuthen 2013). Since Danish companies had no say in the decision to establish a nanoregister, they were not bound by it, and they consequently had little need for self-regulation as a tool to manage its impacts on public perceptions of nanotechnologies. While German companies in the debate over a nanoregister have voiced similar arguments, their capacity to dissuade federal decision-makers against reporting obligations also eliminated the need for the VCI and its members to pursue a more aggressive message.

The varied self-regulatory responses across the four countries are in short rooted in the realities of their chemical control regimes and the different roles companies have assumed in the regulation of nanotech. Since influence in the British and German regulatory systems is purchased through cooperation with state authorities, companies must also assume responsibility for its outcome. The extensive involvement of companies and their associations in the decision-making process in other words encourages them to behave 'responsibly' – and this would include avoiding tactics intended to weaken the legitimacy of joint policies. Industry self-regulation in Britain and Germany thus intends to complement, not preempt, state policies governing the human health and environmental risks of nanotechnologies. In the United States and Denmark,

Table 6.1 Explanations for Industry Self-Regulation in Britain and Germany

	BRITAIN	UNITED STATES	GERMANY	DENMARK
Self-Regulation	Yes	No	Yes	No
State-Industry Cooperation	Yes	No	Yes	No
Plans for Legislation	No	Yes	No	Yes
Public Opinion	Favorable	Favorable	Favorable	Favorable
NGO Campaigns	No	No	No	No
Media Coverage	Episodic	Episodic	Episodic	Episodic
Market Pressures*	Low	Low	Low	Low
Strength of Organization	Low	Low	Very High	High

* Demands for voluntary risk management mechanisms from insurers, investors or business partners.

where companies remain free to contest scientific conclusions and dispute regulatory actions, the need to self-regulate has yet to present itself.

CONCLUSION

Conventional political science answers to the question, why do industries self-regulate, emphasize either a desire to capture the benefits of collective action or the need to deflect costs imposed by external stakeholders. Whether we insist on economic rewards or negative inducements, we usually find reasonable explanations for business interests in self-governance. But not for nanotechnologies. As we have seen in this chapter, the diverging self-governing strategies of industries in Britain, Denmark, Germany and the United States is neither an account of the different control strategies of governments on either side of the Atlantic; nor is it one of the different risk perceptions and thresholds of Europeans and Americans or the organization of business interests in these four countries. It is instead the story of the need to garner stakeholder confidence in nanotechnologies; and how the incentives and constraints embedded in the

institutions of the British and German chemical control regimes have created compelling reasons for companies to self-regulate. Table 6.1 summarizes the empirical record for the different accounts of self-regulation.

Bound by the contingencies of cooperation, UK and German companies embraced self-regulation as an instrument to shelter their operations from future nanoscares, resulting from 'irrefutable' news about nanotech. Because American and Danish companies in contrast have been reluctant to cooperate with governmental decision-makers, they have faced few compelling reasons to self-regulate. This argument presumes that cooperation with state authorities translates into a need for companies to self-regulate. The UK and German nanotech experiences have given us no reason to doubt this link. In view of collective action theory, this is nonetheless a heroic assumption. Free-rider problems, distributional conflicts and inertia usually act as significant barriers to collective action among companies that are ultimately rivals; and such dynamics must of course also infringe on the decision to band together to develop a *common* code of responsible conduct. In essence: would Danish companies have embraced self-governing responsibilities had they cooperated with MST and other state agencies? Perhaps – but it is far from certain. Self-governance presupposes that most if not all members of a group share a common judgment about the harm that might result from their behavior and agreement on the rules intended to correct and avert such harm – neither of which constitute a trivial problem (Ostrom 1990); but none of which has figured in my account of self-governance. Let us consider each in turn.

First, companies will not self-regulate unless they recognize the potential for spillover harms. How do members of an industry arrive at such a diagnosis? One straightforward way companies might become aware of their interdependencies is to *talk* about them. In Britain, self-regulation was thus the result of discussions among a group of companies that came together to explore aspects of responsible governance and good practice for nanotechnologies. In Germany too, the NanoKommission's 'Five Principles for Responsible Use of Nanomaterials' were the result of deliberations among members of Working Group 3. And, just as the NanoKommission has facilitated cooperation among federal officials and industry representative, it has also promoted discussion about joint problems and their possible solutions *within* industry. Deliberative institutions in other words not only underpin cooperation among state bureaucrats and industry; they may likewise encourage collective action among companies. A closer look at the different organizational basis for dialogue among German and Danish companies further probes the roots of their diverging self-governing strategies.

In 2003, VCI with the German Society for Chemical Engineering and Biotechnology, DECHEMA, established a joint working group on the 'Responsible Production and Use of Nanomaterials'. As an interdisciplinary forum for academic and industrial experts, the group aims to share scientific findings and best practices on safety aspects of nanomaterials. Discussions center on identifying and prioritizing risk research and measures to promote the economic and technological opportunities of nanotechnologies. The group has since published extensively on research needs and priorities, including roadmaps for safety research and papers on the current status of risk assessment (DECHEMA and VCI 2007a; 2007b; 2011). Like the NanoKommission, the working group creates opportunities for participants to gather and exchange information, develop common understandings and craft agreed solutions. Unlike the advisory committees and stakeholder panels we encountered in chapter five, the DECHEMA-VCI group is however exclusively a private forum.[30] The working group in short provides a venue, where corporate representatives can meet to debate the opportunities, challenges and safety aspects of nanotechnology, including the need to garner stakeholder confidence.

In Denmark, by contrast, no such private organization exists; and the absence of institutionalized policy deliberations among industry and state authorities is paralleled by infrequent contacts among corporate representatives. The diminutive size of industry of course implies that the Danish nanobusiness community is relatively small. But while members might know one another, they do not routinely meet to debate scientific and regulatory developments or discuss their problems and options.[31] DI and other business associations have on occasion convened meetings to inform members of national and international developments. But there has been no sustained effort to promote regular discussion through the creation of working groups or professional networks.[32] Absent a venue to organize and encourage ongoing dialogue among representatives of the Danish nanobusiness community, there has been little basis for the development of common understandings of mutual problems and their possible solutions.[33] And it is therefore ultimately doubtful whether Danish companies – had they cooperated with MST and other state authorities – would have embraced self-governing responsibilities. Reflecting on the basis for organizing Danish nano companies, an industry representative thus demanded: "What would they have in common?"[34]

30 Representatives from the federal agencies are on occasion invited to participate, but strictly as observers.
31 Interview, Copenhagen, June 1, 2011.
32 Interview, Copenhagen, March 9, 2011.
33 Interview, Copenhagen, June 1, 2011.
34 Interview, Copenhagen, March 9, 2011.

The different organization of exchanges among companies in Germany and Denmark is on the other hand not alone sufficient to account for their diverging self-governing strategies. Although the NIA for instance was established with the express ambition of facilitating information circulation and discussion among UK companies,[35] groups and fora comparable to those found in Britain and Germany also exist in the United States. The ACC Nanotechnology Panel was for example convened to promote dialogue and contacts among ACC members with an interest in nanotech;[36] and the panel serves much the same basic purpose as the NIA for UK companies.[37] While the basis for discussion among American companies thus is not distinguishable from the situation in Britain, talks of self-governance never surfaced and no initiative comparable to the Responsible NanoCode have been undertaken. Rather, to understand why industry leaders in the two countries perceived the need to self-govern differently, we must instead look to the different roles companies have assumed in the regulatory process. Private deliberative fora are in contrast best understood as a prerequisite for companies to recognize their interdependencies; and therefore for the decision to act upon them (Culpepper 2003). Whether cooperation with state authorities will also result in self-governance depends in short on the capacity to organize and promote dialogue about joint problems and their possible solutions.

Second, this of course leaves the question of how companies were able to agree to rules intended to govern their behavior. It is after all one thing to reach common understandings of joint problems; quite another to devise agreed solutions and still another to ensure that everyone adheres to them. At the heart of the collective action dilemma is the free-rider problem – and such problems should be especially pronounced for members of the nano industry given the vast number of companies involved (Olson 1971). Yet, despite the risk of free-riding, companies in both Britain and Germany readily came together to implement a common code of conduct. The interpretation of self-regulation advanced in this chapter can help us understand how companies were able to solve the collective action problem and how this 'solution' in turn had implications for the design of the British and German codes of responsible conduct. Recall that fear of widespread backlash and hence the threat to the commercial viability and long-term legitimacy of nanotechnologies motives the interest in self-governance. But members of the industry do not have the same stakes in preventing this fate. Irreparable damages to market and consumer

35 Interview, London, March 3, 2011.
36 Interview, Washington, D.C., April 18, 2012.
37 Interview, Brussels, March 2, 2011.

confidence will in fact spell very different consequences for the fortunes of large and small companies.

For small startups, whose business model is entirely focused on nanotech, backlash or worse nanophobia will of course prove disastrous. But the long-term commercial prospects of nanotechnologies need not be among their immediate concerns: by the time backlash sets in, they may long have ceased operations – or have been acquired by other companies. For large manufacturers in contrast, signs of market erosion will be alarming. Because they will remain in the market long after the initial hype has died out, large companies must demonstrate a particular concern for the commercial viability of nanotechnologies. Large companies with conspicuous brands will likewise be more vulnerable to visceral consumer and market reactions than their small competitors, which pursue narrow business-to-business applications. Stakeholders often possess better information about large companies – or consumers may simply associate them with nanotech – and they are in consequence at greater risk of being singled out as the target of boycotts, even though their performance might not be below the industry average (King, Lenox and Barnett 2002: 395f.).

Large manufacturers will in other words suffer exposure to the fallout from adverse information related to their competitors, even if such information does not directly pertain to them or their products. Although unilateral commitments might reduce such exposure, they cannot eliminate it entirely either. Since the costs of spillover harms – and the benefits from measures intended to mitigate them – thus are asymmetrically distributed among large and small companies, the nano industry is reminiscent of a privileged group (Olson 1971): large companies have the resources, expertise and incentives required to initiate instruments intended to ensure market confidence in industry and public acceptance of nanotechnologies (Barnett 2013: 220; Prakash and Potoski 2007: 783); and self-regulation was in both Britain and Germany driven by the demands of large companies able and willing to assume the cost of developing codes of responsible conduct. Herein lies perhaps also the key to understand the design of the two self-governance instruments.

An oft heard criticism of self-regulatory regimes is that they neglect to establish mechanisms to monitor and police compliance and hence have limited impact on business behavior. This critique certainly could be – and has been – levied against the British and German codes of conduct: companies in both countries were reluctant to include rigorous enforcement and control measures (RNCI 2008; NanoKommission 2010b), and neither the British nor the German code of conduct confer obligations on participants. But if large companies had the incentives to initiate the development of codes of conduct, why were they then reluctant to make binding

commitments? A tentative answer might run along these lines: Because 'bad news' might engender backlash, anticipating such information will also be an essential element of the solution. Companies could conceivably have done so in one of two ways: manage the perceptions of stakeholders by communicating information about members of the industry and the technology *or* improve their collective performance relative to criteria of concern to stakeholders. These responses to the problem of information asymmetries among companies and their stakeholders however place very different demands on the capacity to curb free-rider dynamics.

A self-regulatory regime can reduce the risk of spillover harm by helping stakeholders distinguish members from nonmembers. If participation in such an industry 'club' conveys information about the desirable but otherwise unobserved characteristics of members, it might act to shelter members from criticism and hysteria in the wake of a future nanoscare (Barnett and King 2008: 1156). By making a commitment to proactively and effectively mitigating any risks related to nanotechnologies, self-regulation might in other words allow members to distance themselves from potential culprits. To be credible in the eyes of stakeholders, such an elite subgroup must however make *binding* commitments. Failure to correct the behavior of concern to stakeholders would dilute the credibility of their commitment to do so, and members must therefore be ready to establish mechanisms to police and compel participants to adhere to program obligations; and there must be a mechanism to expel or exclude those unable or reluctant to meet their obligations (Prakash and Potoski 2007).

But to the extent that a binding self-commitment to responsible governance succeeds in averting backlash, garners public acceptance and strengthens market confidence, all members of the nano industry – whether they subscribe to this commitment or not – will benefit. Incentives to free-ride will in consequence dominate. Membership of such an elite club would likely remain small, with industry at large left with little incentive to join. What positive impact information about participants might have on stakeholder perceptions would likely be outweighed by information about their competitors, who do not participate. No more than spillover harms can be eliminate through unilateral commitments, so binding commitments among a small group of (large) companies would be sufficient to shore up stakeholder confidence, if the large majority of (small) companies continue to engage in actions that erode favorable perceptions of nanotechnologies. Unless participants could find a way to convince their competitors to join, implementation of binding commitments would occur at their expense and to the collective benefit of members and nonmembers alike.

Given the persistence of free-rider dynamics, coupled with the significant hurdles of finding common ground among companies scattered across various and diverse market sectors, it is

hardly surprising that companies were reluctant to commit to binding standards. While large companies do have disproportionate stakes in the long-term market potential of nanotechnologies, the benefits of rigorous enforcement and control measures would not have outweighed their costs. German and UK companies in consequence opted for a less demanding solution to the problem of spillover harms: rather than agree to establish mechanisms to monitor and police behavior, their codes of conduct instead intends to familiarize stakeholders with the industry and the technology, such that future bad news is viewed to reveal little or no new information of relevance and so have limited impacts on stakeholder perceptions. Since their codes of conduct may reduce the harmful effects of interdependencies to the collective benefit of the nanobusiness community, German and UK companies would in short appear to have provided a 'public good' to the industry as a whole – albeit at limited cost for participating companies. This chapter then again emphasizes that fear of state intervention need not be the dominant driver of business behavior. Rather, the chapter speaks to the need for members of an industry to garner stakeholder confidence, and demonstrates how the desire to mitigate spill-over harms stimulates their interest in self-governance.

CHAPTER SEVEN

Better Living through Nanotech?

Chapter one opened with the observation of a *de facto* industry moratorium on the use of nano-remedial techniques in Britain. Since 2004, UK-based and international practitioners have observed this moratorium as a result of an official request by HM Government that industry avoid the deliberate release of nanoparticles into the environment until their effects and possible risks have been assessed. A decade of safety research has not unearthed conclusive evidence that nanoscale particles present significant, unreasonable or unmanageable risks to human health or the environment. But it has not managed to acquit them of suspicion either. The pervasive uncertainties about risks, benefits, properties and future directions of nanotechnologies persist – and are likely to do so, given the intricate scientific, technical, commercial and regulatory complexities associated with nanoscale materials. 2014 will thus mark the decennial of industry's voluntary moratorium on nano-remedial techniques; and still there are no signs that it will come to an end in the foreseeable future. While remedial projects using nanoscale particles now are under way in other countries, neither UK-based nor international operators appear to have imminent plans to use such tools in Britain (Bardos *et al.* 2011). So why do companies abide by a voluntary moratorium in the United Kingdom? Chapter one observed that neither the scale of environmental contamination in Britain nor technical, financial or administrative impediments can account for the discrepancies between the UK plans of practitioners and their international business strategies. But the nature of bureaucratic commitments in Britain can.

In chapter four, we saw how centralization of power in Whitehall dictates a strategic orientation towards the executive bureaucracy. Confronted with the uncertain promises and risks of nano-remedial techniques, regulators at Defra and the UK Environment Agency responded cautiously, recommending that industry refrain from deliberate releases of nanoparticles. Beyond this request, however, HM Government has yet to decide whether and how the use of nano-remedial tools will be authorized. Nothing thus prevents companies from submitting nano-remedial projects for administrative approval. Nonetheless, no such application has been received

to date. Not because the licensing procedure is exceedingly burdensome by international standards, however; but because the procedure commits the details of authorization to the discretion of state bureaucrats. Hence, until regulators at Defra and the UK Environment Agency are convinced that nanoscale materials do not represent unreasonable risks to human health or the environment, companies stand to gain little from attempts to force a decision by submitting project applications. Rather patience appears prudent as evidence in support of a decision to authorize nano-remedial techniques is gathered, developed and interpreted. But this of course does not imply that companies must resign to await state initiative.

As we have seen, UK policies for bridging the knowledge gaps exhibit a penchant for drawing in industrial expertise to inform decisions on the proper course of action. Chapter five thus demonstrated how the extensive reliance on expert bodies and stakeholder fora in the development of UK chemical safety policy afford industry representatives opportunities to mold the knowledge of state bureaucrats and hence influence their understandings of the need for and design of new regulations. Companies inclined to volunteer information, share their expertise or assist regulators in the acquisition of new knowledge may in turn exercise significant influence on regulatory priorities and policies. Applying for administrative approval of nano-remedial projects might of course succeed in persuading state bureaucrats of the virtues of the techniques; but it could also fail. Pushing for state authorities to decide whether the use of nano-remedial tools will be authorized or not – by submitting projects for approval – in other words represents too blunt an instrument to guarantee a decision that favors corporate interests. UK companies must instead rely on their access to administrative deliberations to advocate the merits of nano-remedial techniques, pressing on decision-makers their concerns about scientific developments, technical feasibility and economic impacts.

At the same time, regular contacts and dialogue among representatives from industry and state authorities help bolster corporate confidence that their views will be considered as new issues emerge. UK companies can thus countenance a gradual and precautionary approach to nano-remediation, confident that an eventual decision to authorize the use of nanoscale materials and the rules governing authorization will consider their inputs and – where possible – accommodate their interests. A voluntary moratorium on the use of nano-remedial techniques was therefore an industry response that grew from the demands placed on corporate decision-makers by the realities of the British regulatory system. While governmental decision-makers in the United States and other European countries meanwhile share the cautiously optimistic view of nano-remedial techniques expressed by their UK peers, their regulatory institutions and processes also structure the opportunities for national and international operators differently. Gaining and

maintaining influence over regulatory outcomes in these countries confront businesses with a distinct set of incentives and strategic demands – and thus hints at the reasons for the discrepancies between the UK plans of practitioners and their international business strategies.

Whether our interest is narrowly confined to the politics of environmental remediation or to the more general process of nanotech regulation, the findings of this thesis point to the same conclusion. In all four countries, business responses to governmental appeals for voluntary data disclosure, joint safety research and cooperation to inform the formulation and implementation of national nanotech policy reflect tailored attempts to navigate the strategic environment for chemical control policy. The varied responses of industries in America and Europe is thus not an account of variations in governmental control strategies for nanotechnologies, the organizing logic of political economies, or differences in stakeholder perceptions of nanotech on either side of the Atlantic. It is instead a story of the incentives created by the institutions that underpin relations among state bureaucrats and industry; and how variations in the institutions and processes of domestic chemical control regimes have shaped business responses to the evolving regulatory process. This final chapter revisits my theoretical arguments in light of the empirical cases as well as how they might apply to other countries, industries and technologies. I also consider implications for our understanding of the regulatory behavior and interests of business, including the instrumental value industries attach to self-regulation. I conclude with some reflections on the ability of governments to assess and control chemical hazards.

BUSINESS INTERESTS AND THE POLITICAL PROBLEM OF COMMITMENTS

I have traced the roots of the varied industry responses in America and Europe through two case studies that examined how the institutions and processes of national chemical control regimes link to the strategic risk-benefit calculations of companies. In chapter four, I demonstrated how the autonomy of administrative authorities to decide regulatory outcomes, insulated from pressures originating from other branches of government, explains the reactions of companies in the Britain and the United States. Chapter five next explained how the different responses of German and Danish companies are rooted in the institutions that structure communications among state actors and industry representatives. And I further demonstrated how the strategic environment for chemical safety policy in Britain and Germany is comparable; and how the coincidence of business responses in these two countries is explained by the capacity of state bureaucrats to commit to cooperation with industry.

Table 7.1 Overview of Drivers of Business Responses and the Outcomes of the Regulatory Process in American and Europe

	BRITAIN	UNITED STATES	GERMANY	DENMARK
Regulatory Strategy	Encourage cooperation	Encourage cooperation	Encourage cooperation	Encourage cooperation
Business Response	Disclosure	Nondisclosure	Disclosure	Nondisclosure
Nature of Bureaucratic Commitments	Credible	Ambiguous	Credible	Ambiguous
Regulatory Powers	State bureaucrats endowed with broad discretionary authority	State bureaucrats enjoy limited discretionary authority	State bureaucrats endowed with broad discretionary authority	State bureaucrats endowed with broad discretionary authority
Nature of Advisory Proceedings	Comprehensive industry participation and representation	Limited and formalized contacts among industry and officials	Comprehensive industry participation and representation	Limited industry participation and representation
Legislative Control Strategy	Regulate nanotechnologies through existing legislation	Regulate nanotechnologies through existing legislation	Regulate nanotechnologies through existing legislation	Amend existing legislation to regulate nanomaterials
Mobilization of Public Opinion	No	No	No	No
Impact of REACH on Decision-Making Process	Minor	Negligible	Minor	Minor
Political Strength of Chemical Industry	Moderate	Moderate	Strong	Weak
Outcome	Joint Decisions	Governmental Inaction	Joint Decisions	Unilateral Regulations
Examples	HSE guidelines drafted and agreed with industry New test and risk management methodologies established through joint research ventures	Significant new use rules governing notification of nanomaterials	BAuA-VCI guidance documents AGS TRGS on nanomaterials New test and risk management methodologies established through joint research ventures	New mandatory registration requirements
Implications for Business Interests	Business predictability Best practice guidelines Stakeholder confidence	Business predictability Lack of test methods and statutory guidance documents	Business predictability Best practice guidelines Stakeholder confidence	New administrative burdens Market uncertainty Risks of backlash

Table 7.1 summarizes the drivers of business responses to the regulatory process and its results across the four countries (classified according to the 'outcomes' sketched in chapter two). While American, British, Danish and German companies have pursued widely different strategies, they have also met with comparably satisfying results in terms of moderating production costs, reducing barriers to market entry, protecting the potential for innovation and assuring confidentiality. Regardless of their varied interests and styles, companies have been motivated by what we can describe as a quest for certainty: although their responses and behaviors may differ, companies have in each country sought clarity regarding their statutory obligations, market confidence in their products, public acceptance of the technology and technical command of its scientific principles. And, over the decade since 2003, state intervention has translated into a more stable and hence predictable regulatory environment, so to recall the words of a U.S. industry insider "it is not nearly as intimidating as it used to be."[1]

Regulators for their part have on one hand sought to balance the need to identify and control possible risks with the desire to encourage the technology's economic and societal benefits on the other; and, in the main, national nanotech policies have succeeded in striking a delicate balance between these dual goals. An official summed up the rationale governing UK control strategies:

> "It as an evidence-based approach. We are monitoring the science and responding to clear evidence of harm. And also we want to capture the benefits [so] securing the benefits and managing the risks. […] It is possible to be overly precautionary and stifle innovation and we are not in the business of doing that. […] There are some great ideas coming out of this country, which we are rightly proud of and we don't want to stifle that. We don't want those ideas to go overseas, when we can capitalize them at home." [2]

The absence of conclusive evidence that nanotech presents unreasonable risks has at the same time spared governmental risk managers from the dilemma that often arises when protection of health and safety comes at the expense of industry's potential to innovate and compete. With the exception of Denmark, regulators have favored a case-by-case approach that has imposed few new costs or compliance hurdles on industry. In Denmark, administrative deliberations and interpretations, coupled with the absence of major producer interests, ultimately led decision-makers to accept increased business costs in exchange for measures to improve the evidence-base on nanomaterials. Yet, while some regulators, notably U.S. EPA and UBA, now likewise advocate the need for mandatory instruments, others do not. Nanotech has yet to bring governments in a situation, where evidence of unreasonable risks necessitates rigid restrictions on industry's

1 Interview, Washington, D.C., April 16, 2012.
2 Interview, London, March 3, 2011.

freedom to operate; and it therefore remains to be seen how they will trade off one goal for the other, when their policies cannot accomplish both simultaneously.

In each country – save perhaps in Denmark – the regulatory process thus brought greater business confidence and predictability, while the formulation of statutory guidance documents and joint risk management methods in Britain and Germany over the longer term might facilitate what the U.S. insider also called for: "widespread stakeholder buy-in on the safety front."[3] Despite the different political contexts and the varied outcomes of the regulatory process, companies have at the same time ensured that disclosed information was not used to the detriment of their interests – an observation that lends *prima facie* credence to the claim that the nature of bureaucratic commitments weighs heavily on corporate decisions to disclose, bias or withhold information from the authorities responsible for regulating their conduct.

How confident can we be that the capacity of state bureaucrats to make credible commitments is indeed responsible for the observed patterns of industry behavior across these four countries? Relationships among regulatory authorities and business actors constitute one dimension, albeit an important one, of a nation's public policy process. But other circumstances and contingencies also impinge on the political behavior of business – and the varied political contexts for nanotech regulation suggest that other variables might perhaps better explain the different industry responses. I have relied on a twofold approach to eliminate possible ambiguities concerning the causal drivers of the varied business strategies and behaviors. First, I have sought to explicitly consider the most important alternative explanations that might be relevant to the observed outcomes, including the impact of EU competences on regulatory decision-making in the UK chemicals sector, mobilization of public opinion or the legislative control strategies of governments in America and Europe. To reiterate, neither of these rival accounts offer a satisfactory explanation of the different business responses.

Second, I have approached the question of control for confounding variables according to the logic of a *most similar systems* design. Hence, beyond variations in their institutions and processes of chemical control policy, the country studies juxtapose broadly similar cases. We can as I observed in chapter one therefore safely assume that the varied business responses do not reflect calculated attempts to counter distinct bureaucratic or legal traditions. For the same reason, we can feel equally confident that the organization of their political economies and their traditions of state-society relations are not responsible for the different industry responses. Neither do

[3] Interview, Washington, D.C., April 16, 2012.

variations in the relative size, economic weight and political strength of the national chemical industry bring the conclusions drawn from the case studies into question. In chapter five, I explained that while the diminutive size of the Danish chemical industry undeniably influenced its response to the regulatory process, it did not determine that response. The economic and political weakness of the chemical industry in Denmark is rather a precondition for understanding the roots of the acquiescent response of Danish companies – just as the reactions of their German competitors can be understood in relation to the chemical industry's privileged political position that resulted from its postwar economic success in Germany. The particular history, organization, and economic strength of the domestic chemical industry do of course have implications for its political options and behavior – but this does not translate into predetermined strategies for meeting regulatory challenges.

We can further bolster our confidence in this conclusion by looking to the behavior of multinationals. International firms have in each country readily adopted the strategies and positions of their domestic competitors. Consider the record of joint safety research. In chapter three, we saw how public-private partnerships constitute a cornerstone of British nanotech policy, as exemplified by the PROSPEcT project – a consortium that brings together government agencies and research institutions, university laboratories and industry as joint sponsors. Corporate sponsors include Oxonica, a small spin-off from the University of Oxford, several other UK-based companies, U.S. multinational Johnson & Johnson and German chemical giant, BASF. At home, BASF has likewise been among the core sponsors of the German NanoCare cluster projects. Despite the high stakes riding on company test data, concerns for confidentiality or regulatory liabilities have not served to deter the company from collaborating with state authorities. In the United States, however, BASF has undertaken such commitments to joint safety ventures on a much more modest scale. BASF do participate with U.S. manufacturers in the NanoRelease project. Unlike the PROSPEcT or NanoCare projects, which aim to provide a full characterization of the analyzed nanomaterials, NanoRelease is however meticulously crafted to minimize access to the raw data needed to lift the burden of demonstrating unreasonable risk. Whereas BASF thus has expressed no reservations in cooperating closely with regulators in Britain and Germany, the company also mimics its American competitors in their manifest discomfort in disclosing sensitive information to the federal agencies. The participation of Johnson & Johnson in the PROSPEcT project on the other hand provides an illustration of how U.S. multinationals embrace the strategies of the European competitors. American no less than European multinationals, then, appear to recognize that influence in regulatory politics is maximized by exploiting existing national processes to their full advantage.

The case studies do of course contrast countries with very different political systems. Constitutional and political variables undeniably impact on regulatory politics, and they likewise influence the political options and strategies of business. Might not the federal American system for example create different opportunities for businesses than the unitary British system – opportunities, which could have a different bearing on the strategic risk-benefit calculations of companies in the United States than in Britain? Or perhaps variations in the kind and intensity of contacts companies cultivate with political parties influenced their responses to the regulatory process? The German chemical industry for example entertains close ties with the FDP and the CDU. Danish trade associations in contrast tend to pursue less clear-cut partisan strategies. With parties traditionally viewed as unequivocal allies of industry at the helm of government, might German companies therefore not have been presented with more generous opportunities to influence policy outcomes than their Danish competitors? Because the country studies thus consider regulatory processes that unfold within very different constitutional and political contexts, they may fail to convince the skeptical reader that other variables and circumstances are not relevant to – or at least impact on – the observed patterns of industry behavior. Juxtaposing evidence from all four countries can allow us to settle possible ambiguities concerning the proper interpretation of the varied industry responses.

In chapter five, I observed that despite their distinct constitutional traditions, the nature of legal and institutional relationships found in the German and Danish chemical control regimes are comparable. The different business responses I argued therefore cannot reflect variations in the prospect of political or judicial interference in regulatory proceedings. This assessment is nonetheless somewhat inaccurate and the decentralized nature of the Federal Republic does have implications for the strategic options available to business groups in Germany. In the past, the VCI has thus proven admirably adroit at enlisting the support of Länder governments to influence outcomes at the federal level (Paterson 1991: 238). The unitary Danish political system in contrast precludes companies from seeking influence through such a subnational route. Did their leverage with regional governments have a bearing on the responses of German companies? The evidence I have considered suggests not. While representatives from the Länder participated in the policy process, there are no evident signs that German companies have sought to enroll their support – or that the prospect of doing so have figured prominently in corporate risk-benefit calculations. Looking to the other federal system in my sample – the United States – help eliminate doubts that variations in the distribution of powers among national and regional entities account for or otherwise distort the interpretation of the case studies.

Similar to the German Länder, the U.S. states retain important powers with respect to chemical safety policy. Under TSCA, however, the control of toxic substances is a clearly defined federal competence; and attempts to exploit their leverage in state capitals to browbeat EPA and other executive agencies into submitting to industry demands hold limited promise for American companies. Quite the opposite in fact. In chapter six, we saw how the slow pace of TSCA reform has induced state legislatures to initiate chemical or product-specific measures in record numbers – many with explicit provisions for nanomaterials (Bergeson 2012b). Rather than turn to state capitals for support, reform initiatives in California and other U.S. states have instead meant that U.S. companies had to divert their attention across multiple jurisdictions. But this has not evidently affected how corporate decision-makers viewed or responded to policy developments in Washington. The constitutional structure of political systems does of course influence how private interests orient their attention and allocate their resources. Responsibility for nanotech has nonetheless in all four countries fallen squarely within the statutory ambit of *national* authorities. While the potential to enlist regional governments against federal bureaucrats exists for companies in Germany and – in principle – the United States, there is ultimately little evidence to suggest that corporate decision-makers in either country have looked to this option to influence the direction of federal nanotech policies.

Neither do the cases lend weight to an interpretation that parliamentary dynamics have shaped the responses of industry. The four countries do differ in the nature and character of their partisan politics; and might further be distinguished by the kind of ties and relations businesses seek to cultivate with party organizations. But variations in their partisan strategies have not impacted on how companies responded to the evolving regulatory process. As we have seen in chapters four through six, nanotech has drawn little partisan attention and has not sparked competitive dynamics among political parties. This is hardly surprising: unlike economic or health care policy, questions of chemical safety, by virtue of their technical obscurity, rarely invite partisan contestation. Elected politicians – with the exception of U.S. law-makers – routinely relinquish their prerogative to decide and interfere in the formulation and implementation of chemical safety policy. But while the NNI agencies have been the target of congressional scrutiny, federal nanotech policies have not emerged as a contentious issue in either House or Senate. Where nanotechnologies did become an issue for parliamentary debate – Denmark – industry was unable to count on the sympathy of the liberal-conservative opposition to prevent the passage of a narrow political agreement on a nanoregister. Contacts and influence within political parties may well afford industries opportunities to place a break on meddling bureaucrats. But there are nonetheless few convincing signs that companies have looked to

political parties for sympathy in dealing with their regulatory adversaries; or that variations in the support they might draw from such contacts should have influenced their responses to the regulatory process.

The cases are not monolithic, however. In all countries, we find instances of collaboration with or dissociation from governmental officials, disagreement and compromise, disclosure as well as nondisclosure. Even in the United States – a country renowned for its 'longstanding culture of antagonism between the industry and the government on these kinds of issues'[4] – we observe examples of cooperation among regulators and companies; as do we find instances of suspicion in Germany, despite the 'long history of cooperation between the federal agencies and industry.'[5] While interactions among state bureaucrats and industry representative in each country fall in relatively clear patterns, nanotech cannot be taken as testament to enduring national styles of regulation or deep-seated traditions of government-business relations. Rather the varied business responses across and within the four countries align with the incentives created by the specific institutional configuration of their respective chemical control regimes. U.S. companies for example readily volunteered information to NIOSH, exactly because the agency's research mandate guaranteed that participants would not incur regulatory liabilities. German companies for their part were in contrast reluctant to cooperate with UBA, since the absence of institutionalized policy deliberations left them without a reliable basis to predict how disclosed information might be put to use by the agency. Expectations about the probable behavior of state authorities in short informed the strategies of companies in each country; and shaped their reactions to the specific opportunities offered by participation in the regulatory process.

Looking beyond these four countries, there is thus little immediate reason to believe that the regulation of nanotechnologies in other political contexts should yield dissimilar results. Certainly, the dynamics of chemical control policy outlined in chapter two also apply in Australia, Canada, France and other advanced industrial economies. To the extent that governmental decision-makers in these countries have embraced comparable policies and priorities for nanotech, an investigation of their regulatory processes can therefore be expected to unearth similar results with respect to the drivers of business responses. Whether Australian, Canadian or French authorities can persuade companies to volunteer information necessary to assess the risks of specific nanomaterials or decide on effective control policies hinge on their capacity to convince companies to entrust them with sensitive information. And this capacity will derive from how

4 Phone interview, April 3, 2012.
5 Phone interview, October 30, 2012.

these countries organize and manage their institutions and processes of chemical control – in particular the distribution of regulatory powers and the reliance on deliberative institutions in the formulation and implementation of national chemical safety policies.

Whether companies will decide to disclose, bias or conceal information in short depends on the expected behavior of their regulatory adversaries and the credibility of their commitments. But this is not a conclusion unique to nanomaterials. To succeed in regulation of complex social and economic processes, states require vast amounts of information on the possible and actual consequences of their policies. From environmental policy over worker protection to the regulation of competition, state authorities in almost all contexts need more information than they have. And more often than not the information needed to make regulatory decisions can be supplied only by the very companies and industries, state authorities are looking to control. For all their novel properties, nanomaterials are from a regulatory perspective thus familiar in at least this one respect. The delicate issues raised by the regulation of nanotechnologies with respect to whether or not companies should trust state bureaucrats with sensitive information are in other words an expression of the more fundamental problem of commitments in politics.

At the root of the commitment problem is the state's discretionary powers (North and Weingast 1989; Shepsle 1991). State policies often depend on the behavior and cooperation of private actors to meet their objectives. Policy preferences however also change over time, and while policy-makers may wish to encourage cooperation with social and economic actors to achieve their goals, their incentives after the fact are not always compatible with maintaining a cooperative agreement. Unless governments can devise a method to disable their discretionary powers, individuals, groups and industries must doubt their commitments to pursue a set of stable and predictable policies. Yet, when governments cannot rely on coercion to implement their policies, a lack of credibility becomes problematic: if future policy changes can be anticipated, social and economic actors may fail to react and adapt as intended, thus preventing the policy from attaining its objectives (Majone 1996; Gilardi 2002). And the capacity of state actors to make credible commitments is therefore as relevant for the control of chemicals as it for macro-economic policy-making, labor-market policy and all other governmental policies, where intervention aims to influence the behavior of individuals, groups and industries.

For many areas of state intervention – from the licensing of new substances for environmental remediation to the approval of new drugs – elected politicians are content to leave effective decision-making powers firmly in the hands of executive departments and agencies. In these areas too, we can therefore expect that the nature of bureaucratic commitments will exercise a major influence on the political behavior and strategies of businesses. Although different

institutional arrangements may well buttress the capacity of state bureaucrats to commit in other areas and for other issues than industrial chemicals, expectations about the probable future behavior of the agencies responsible for regulating their conduct should nonetheless weigh heavily on corporate risk-benefit calculations. Unless state bureaucrats can credibly commit to regulatory policies, companies must be cautious of sharing information about their operations.

But the framework I have elaborated to dissect the determinants of business strategies is not applicable to all areas of state intervention, of course. Although executive bureaucracies are prominent representatives of the state, other governmental or political actors are often more important for deciding the course of a nations policy process. In areas and policy sectors dominated by partisan contestation or political dynamics other than administrative law-making, the nature of bureaucratic commitments need not be relevant to the strategic risk-benefit calculations of businesses. Where for example elected politicians reserve their prerogative to routinely decide and interfere in the formulation and implementation of state policies, it will be more relevant to investigate the institutions and processes that hamper their temptation to alter policies that run counter to their short-term electoral interests. Labor-market policy or macro-economic policy-making thus comes to mind as instances, where constitutional and political constraints on the policy-making powers of governments are much more important determinants of their capacity to commit to a set of stable and predictable policies. While concentration of regulatory authority and deliberative institutions facilitate the capacity of regulators to commit in the industrial chemicals sector – and perhaps in other areas of state intervention as well – other institutions and process also contribute to the capacity of state actors to make credible commitments. An analysis of the political problem of commitments in policy sectors beyond industrial chemicals must in short begin by locating the locus of the state's discretionary powers and then proceed to consider the institutional arrangements that allow state actors to convince their constituents that they can be trusted to honor them.

As a broader theme to my inquiry, I have finally emphasized that fear of state intervention need not be the dominant driver of business behavior. Although industries are commonly held to resist statutory regulations, business also has preferences for and stakes in the outcomes of regulatory politics that extends beyond the desire to minimize state interference. Because a mix of scientific and legal uncertainty can combine to significantly impair the economic prospects of an industry, its members usually have reasons to welcome regulatory outcomes that can help them navigate an uncertain business environment. I base this claim on observations of the chemical industry. As explained in chapter one, I have devoted particular theoretical and empirical attention to chemical companies, because – to paraphrase a German official – this is the industry

'where they really use nanotech, not where it is only an idea to use it.'[6] As the primary targets of regulation, the views and interests of representatives from the chemical industry have necessarily taken center stage in my account of international efforts to assess and control the human and environmental risks of nanotechnologies.

The chemical industry is no friend to state intervention as the record of its members' resistance to TSCA and REACH can surely attest to (See *e.g.* Collins 2010; Selin 2007). Nonetheless, the inconclusive status of nanomaterials under existing statutes and regulations has also presented companies with other opportunities and predicaments than a mere desire to reduce state interference. The main benefits secured by American and British companies can thus be described in terms of the confidence created by a predictable regulatory response to nanomaterials; and similar corporate preferences permeate my narrative of the German and Danish regulatory processes. The roots of these preferences are simple, if multifaceted. Because the science is continuously evolving, the harmful properties of nanomaterials may not become apparent until years or even decades after they have been placed on the market. Absent official guidance, however, companies – as well as investors and insurers – are left guessing about their eventual degree of liability exposure (Fink 2007; Dana 2010). Unless measures are undertaken to address such uncertainties, the funding stream for nanotech might rapidly dry up. Without clear regulatory guidelines, companies likewise struggle to effectively demonstrate the safety of their production processes and products; and this may eventually scare off consumers and deter business partners, reluctant to invest in products with unknown effects or uncertain risks.

While companies thus for obvious reasons may wish to reduce regulatory burdens, a stable regulatory environment also promises significant benefits in terms of business predictability and public acceptance of nanotechnologies, which cannot easily be ignored. The response of Danish and U.S. companies to new statutory obligations illustrates: in what might appear a strange reversal of industry roles and reactions, the decision to introduce registration requirements in Denmark was met with widespread protests, while the responses of U.S. companies to the promulgation of significant new use rules regulating a nanomaterials entry into the market can best be characterized as acquiescent. Rather than any inherent resistance to state intervention, the different reactions of Danish and American companies however owe more to their desire to balance regulatory costs against a predictable business environment. Hence, whereas the Danish nanoregister imposes new administrative burdens on manufacturers and importers of

[6] Interview, Dortmund, October 11, 2012.

nanomaterials and creates uncertainty concerning their eventual obligations and compliance costs, SNURs in contrast ensure a predictable regulatory response at negligible cost to industry.

The chemical industry is nonetheless an industry like no other. Chemicals are indispensable for industrial production, and with both direct and indirect links to almost all industrial sectors, the industrial chemicals sector is one of the most central industries of the modern economy. The economic circumstances and technological contingencies of an industry undeniably affect the (regulatory) interests of its members and the drivers of their behavior (Hollingsworth, Schmitter and Streeck 1994). We should in other words exercise caution before we let conclusions inferred from observations of the chemical industry color our understanding of the interests and behaviors of other industries.

Chemical manufacturers have a long history of resisting statutory obligations that might increase costs, erect barriers to market entry or result in lower or changing patterns of innovation – the lifeblood of the industry. But exactly because it is so highly capital intensive, the industry also places a premium on regulatory certainty in order to ensure adequate investment levels. While testing obligations for example raise the costs of bringing new products to market, manufacturers also demand a predictable regulatory environment to avoid undertaking expensive and long-term R&D for applications that may later be banned. The manufacture and sale of chemicals is further highly internationalized. Rather than cope with a multitude of different requirements, industry leaders has in consequence long expressed interest in harmonization of divergent national policies to ensure coordination of testing protocols and marketing obligations. Fear that REACH could act as a significant barrier to market entry was thus a major concern for U.S. manufacturers, just as TSCA was for their European competitors three decades earlier (Brickman, Jasanoff and Ilgen 1985: 224f.; DiGangi 2003). Although the chemical industry time and again has fought hard against state interference, the industry's economic circumstances and technological contingencies also imply that certain regulations and statutory outcomes are indeed desirable for its members.

But while these features help distinguish the chemical industry, they certainly do not render it unique. Chemicals is not the only product sector, where success is defined by the ability to innovate and continuously bring new products to market; neither is the industry's international character distinct; nor is chemicals the only economic activity, where investments and business planning require companies to operate with extended time horizons. Many if not all of these contingencies in fact characterize industries as diverse as automotive, pharmaceuticals, energy and semiconductors to name but a few. And no less than the chemical industry, members of these industries routinely seek and promote state decisions that translate into greater regulatory

certainty, harmonization of national policies and hence a more predictable business environment. We should in conclusion be cautious of the view that industries will automatically and necessarily resist any and all regulatory restrictions. We must instead consider how specific state decisions and policies might advance – or harm – the interests of regulated industries; and how this in turn shapes the strategies and tactics their members deploy.

INFORMATION, INTERDEPENDENCIES AND INDUSTRY SELF-REGULATION

Chapter six unpacked the narrative of nanotechnologies and industry self-regulation. I demonstrated how the roots of the varied self-governing responses of industries in Britain, Denmark, Germany and the United States lie with the different roles companies have assumed in the regulation of nanotech. And how the UK and German codes of responsible conduct intend to shelter companies from future nanoscares, resulting from 'irrefutable' information about their products and activities. Because so little is still known of the technology's risks and benefits, stakeholder perceptions are volatile and subject to rapid change; and the predicament facing industry is thus one of managing perceptions of nanotech risks and benefits. But this predicament looks very different for companies that cooperate with state authorities and those that do not. Since influence in the British and German regulatory systems is purchased through cooperation with state authorities, companies must also assume responsibility for its outcome – and avoid tactics intended to weaken the validity of joint safety studies or the legitimacy of agreed regulatory solutions. UK and German companies in consequence embraced self-regulation as an instrument to reassure their stakeholders that scientific developments and regulatory outcomes do not reflect the inherent harmful properties of nanotechnologies. Because American and Danish companies in contrast have been reluctant to cooperate with governmental decision-makers, they have no responsibility for regulatory decisions or government-sponsored safety studies; and they can therefore say what they please about them. Free to contest scientific conclusions and dispute regulatory policies, American and Danish companies have faced few compelling reasons to self-regulate.

This reading of the UK and German codes of responsible conduct views self-regulation as a strategy crafted to manage and mitigate the harmful effects of interdependencies among members of the 'nano' industry. Companies commercializing nanotechnologies scatter across the entire industrial economy and stakeholders, not least the public, naturally struggle to distinguish one company from its competitors. Assessing the performance and characteristics of individual companies requires massive amounts of information; a daunting and elusive task even for more

resourceful stakeholders, such as regulators or financial analysts. Because their stakeholders do not or cannot relate information to each individual member of the industry, 'nano' companies share a common stakeholder assessment of their character and relative performance. Adverse information about one company will consequently color perceptions about the entire industry and the technology as a whole – and might therefore cause real harm for its competitors.

Information asymmetries among companies and their stakeholders is thus the crucial problem facing industry. If stakeholders possessed ample information on the relative performance of each individual company, then no interdependencies would exist and no spillover harm would occur. The practices and products of companies could be individually, directly and accurately assessed, and stakeholders could reward or punish each company accordingly. Each company would possess a unique stakeholder evaluation and could take unilateral measures to shape that assessment. Though managing the perceptions of their stakeholders would remain a concern for companies, it would not be a common problem for industry (King, Lenox and Barnett 2002; Barnett and King 2008). Information asymmetries and interdependencies are not problems exclusive to nano companies, however. Consider the difficulties stakeholders may face in determining the relative contribution of members of the energy industry to air pollution rates. Energy companies usually generate electricity from numerous power stations. Some of these facilities contribute to air pollution and some do not (*e.g.* wind turbines). Those that do, vary greatly in the air pollutants they emit. How, when, and where pollutants are released further determines their impact on air quality. To assess the relative contribution of each individual company, stakeholders would in other words require information about its power stations, their production technologies and reduction techniques, the nature of their emissions, and the state of the environment in which pollutants are released. But such comprehensive information is rarely available; and members of the energy industry will therefore likewise tend to share a common stakeholder evaluation of their character and relative performance.

Just as the complex and heterogeneous nature of the nano industry intertwines the fates of its members, so information asymmetries among companies and their stakeholders is a reality in most industries. Because information about the activities of one company or group of companies to some degree color judgments about the entire industry, interdependencies and the potential for spillover harms are in other words not unique concerns for nano companies. This observation, then, suggests that the lessons gleaned in chapter six can be employed to understand the predicaments of companies and the drivers of self-governance beyond nanotech. Codes of conduct have in fact often emerged in industries that the public and government perceive lack self-discipline, cannot be trusted, or are inherently unsafe (Nash 2002: 237). In 1979, at a time

when skepticism towards the chemical industry was rivaled only by the tobacco industry, the VCI for example established the *Initiative Geschützter Leben* – since 1986 supplemented with a set of guidelines that commit members to the safe production and use of chemicals – as an instrument to influence public opinion (Grant, Paterson and Whitston 1988: 258f.; Paterson 1991: 235f.). 1979 likewise saw the Canadian Chemical Producers' Association publish a *Statement of Policy on Responsible Care* motivated by the industry's eroding credibility not just with the public, but also with government decision-makers (Belanger *et al.* 2009). Other examples of industries that have embraced voluntary codes in response to mounting public enmity include *e.g.* textiles, paper and pulp, petroleum, mining and forestry. But while interdependencies thus characterize most industries, it does not follow that recognition of the potential for spillover harms will compel companies to self-regulate or that codes of conduct will always represent instruments to manage stakeholder perceptions. It is for example unclear whether the desire to garner stakeholder confidence would induce the energy industry to launch a code of responsible conduct.

The British and German codes of conduct as I have argued intend to mitigate spillover harms by communicating information about members of the industry and the technology itself. Because the risks of nanotechnologies are (perceived as) unknown and potentially catastrophic, accidents will be highly publicized and may hence produce large ripple effects. Even relatively unremarkable incidents, routine regulatory decisions or otherwise innocent scientific result could conjure up images of a sinister technology run amok. Self-regulation was in other words a result of and a response to the particular risk perceptions of nanotechnologies. Risk perceptions are systematically linked to the characteristics of the risk: an accident that claims many lives may produce relatively little disturbance, if it occurs under familiar and well-understood circumstances. Stakeholder reactions will however be stronger, where the risk in question is perceived to be involuntary, uncontrollable or invisible, has a delayed or irreversible effect, is memorable, very uncertain, poorly understood, unfamiliar, unfairly distributed or seen as a harbinger of further and possibly catastrophic mishaps (Slovic 1987) – all elements which characterize nanotechnologies; but not all technologies.

Whereas the technological promise of nanotech – ultimate human control of the very forces of nature – thus lends itself to doomsday scenarios in which nanoscale robots self-replicate out of control ('grey goo'), the conversion of wind energy to electric power does not to a similar degree suggest images of turbines spun out of control as a threat to the future of humanity. Whether and where we will see industries embrace instruments intended to manage stakeholder perceptions will in other words be linked to the characteristics of the technologies underlying their products and processes, and the risks – real or perceived – associated with these technologies. Industries

that rely on more traditional and therefore familiar techniques within engineering, chemistry, physics or biology might find little use or need for such instruments. Here business interests in self-governance will likely derive from fear of state intervention, market pressures or the strength of business organization – although signs of rapidly deteriorating stakeholder confidence in and acceptance of the products and practices of an industry might change that evaluation.

A number of new and emerging technologies – from synthetic biology over robotics to cognitive science and artificial intelligence – are in the meantime being heralded as defining technologies of the 21st century. As these technologies progress from blue skies research to applied science, ensuring public acceptance and market confidence will be of paramount importance to their commercial prospects and survival; more so, if they – as nanotechnologies – involve significant, but uncertain risks and unknown hazards. If these technologies are to avoid the fate of GMOs, stakeholders and especially the public will need to be reassured that companies are proactively and effectively mitigating any risks related to them. For these technologies and the industries which emerge to commercialize them, the catalyst for voluntary initiatives will likely be public skepticism about the introduction of new technologies and the desire to convince public and market stakeholders of the commitment to develop them in a safe and responsible manner.

BUSINESS POWER AND THE CONTROL OF TOXIC SUBSTANCES

Throughout this account of international efforts to assess and control the human health and environmental risks of nanotechnologies, I have adopted the perspective of nanobusinesses – their interests and beliefs, their predicaments and aspirations for the evolving regulatory process. I have demonstrated how the institutional arrangements, which underpin relations among state bureaucrats and industry, weigh on corporate decisions to disclose, bias or withhold information about their products and operations. But what does all this matter for us, the consumers and the public? Should nanotech give us cause for concern? Surely, we gladly embrace nanotech in the form of our smartphones, tablets and other gadgets. And as research in nanoscience and technology progresses, we may in the future come to depend on yet more miraculous and revolutionary products, processes and applications. So why should we concern ourselves with the pervasive uncertainties about risks, properties and future directions of nanotechnologies? Despite the fuss about unknown properties, nanomaterials are responsible for no work-related casualties, no evidence of human harm or environmental contamination. Or why should we care about corporate statements and commitments to develop nanotechnologies in a safe and responsible

manner? After all, "products get approved by an authority or not, whatever the values of a company, because [they] must hand in the data."[7]

We should care. While it is indeed true that little tangible evidence currently links nanomaterials to actual human or environmental harm that is not a guarantee that such evidence will not surface in the future. The record of toxic substance regulation abounds with examples of chemicals once deemed safe for human consumption that later proved highly hazardous, noxious and persistent. Asbestos, PCBs, DDT and CFCs were all considered 'wonder' chemicals – right until their insidious effects on humans and the environment were discovered. Nanomaterials are thus not the first new 'miracle' products introduced by the chemical industry with suspected, but unknown risks. And despite a decade of safety research, answers to important questions remain elusive. Little is still known about the toxicological and epidemiological effects of nanomaterials, their fate and transport in the environment, their exposure pathways, whether they persist and accumulate in food chains or how they might interact with other chemicals. Until we know more about how to answer these questions, caution is in other words merited before nanoscale materials are realized on a broad commercial scale.

Might we then not rest assured that the responsible state authorities will protect our health and safety? We should. And most of the time we can. Authorities in American and Europe have devoted considerable resources to shore up the knowledge base. But the amalgam of scientific, technical, commercial and regulatory complexities continues to confront governmental control strategies with intractable difficulties. Given the sheer number of nanomaterials that are being researched, developed and manufactured as well as the range of parameters – size, shape, composition, reactivity, surface area and chemistry – that might influence their behavior and properties, there is in short no guarantee that things will not slip through the cracks. The promise of the technology itself – that materials at the nanoscale may exhibit novel and unpredictable properties – thus do raise serious concerns over the capacity of existing risk management systems to ensure human health and environmental integrity.

With the ambition of 'getting it right', governmental decision-makers have looked to industry for information to guide the development of efficacious control policies. A core element of American and European nanotech policies thus consists of appeals for dialogue, collaboration and knowledge exchange among state authorities and industry. And as a consequence of this policy of encouraging cooperation, nanobusinesses have assumed a central role in crafting the

[7] Interview, Frankfurt, October 11, 2012.

regulatory response to nanotechnologies. But in attempting to take advantage of industry's superior knowledge, expertise and resources, it is of course also possible for industry to take advantage of regulators, and by extension us, the consumers and the public. As Cary Coglianese (2010: 47) observes: "if regulation [of nanotech] is needed, this is because the interests of business are not fully aligned with the broader interests of the public. As a result, efforts to engage business in regulating business present inherent challenges." Information is the lifeblood of regulatory politics; and the power to disclose, bias and withhold information is a significant source of business influence over the decisions and outcomes of toxic substance control. But the dependence on information produced, held and – selectively – disclosed by industry raises serious doubts about the ability of governments to assess and control the adverse effects of nanoscale materials as well as their larger macro-scale equivalents.

No company of course wants to place a new chemical on the market that it knows to be inherently harmful to humans or the environment. Product liability laws and the prospect of consumer rejection of dangerous substances combine to deter companies from the reckless pursuit of profit (Belinsky 2010). But this does not mean that companies will avoid a fight to *keep* a product on the market, even if adverse effects are later discovered – and the dynamics of chemical control policy suggest that they are superbly well-positioned to emerge victorious from such a fight. The business power which flows from superior information, knowledge and expertise about products and processes would not be a source of concern if data withheld from regulators could be replicated, biased information could be independently verified and companies compelled to disclose the data required to formulate protective standards. But most of the time that is not an option for state authorities.

Chemicals manufacturers and users have significant advantages in cumulative experience, technical skills, access to data, and research capacity, not to mention the fact that they own the production process. And it is virtually impossible for governments to conduct independent research to reproduce this information (Applegate 1991: 299; Wagner 2004: 1642). Nor can governments necessarily count on their powers to compel. Governments can and do pass laws that mandate product disclosure; but it is often extremely difficult to determine whether companies have provided complete responses or not. A failure to make any response will be clear, but omissions, evasions or inaccurate submissions are hard to police, if regulators cannot independently verify the information. Companies in consequence face overwhelming incentives to submit selective, biased, or even false information to satisfy disclosure requirements (Coglianese, Zeckhauser and Parson 2004: 306f.). It should come as no surprise then that despite longstanding commitments to control toxic substances, very little is known about the long-term

health or environmental effects of the vast majority of the more than 100,000 chemical substances currently in commercial use – and new chemicals enter the market daily. This dearth of toxicity and exposure data contributes to widespread appraisal of the failure of chemicals regulation to address the persistent ignorance surrounding the risks of toxic substances (Lyndon 1989; Sachs 2009).

The ambitious new EU chemicals regime, REACH, is in large measure a reaction to these failings of existing toxic substance laws. REACH privatizes information collection, provision and assessment: to place substances on the European market, manufacturers, importers and users of chemicals must demonstrate that risks are adequately controlled or that their socio-economic benefits outweigh the risks. Rather than assume that chemicals are safe until regulators with minimal authority and inadequate resources can prove otherwise, REACH reverses the burden of proof by requiring manufacturers to establish the safety of their chemicals. No data, no market in other words. REACH marks a significant sea change in European Union chemicals policy and is widely heralded as a potential game-changer. REACH however remains at an early stage of implementation; and it is therefore premature to forecast what impact the statute will have on the control of toxic substances. A look to the past might nonetheless offer important clues to the future course of chemicals regulation.

The 1976 enactment of the U.S. Toxic Substances Control Act presents instructive parallels to REACH. TSCA was not always the 'toothless tiger' it appears today (Collins 2010). As originally conceived, TSCA was a regulatory powerhouse of a broadly precautionary nature; and one of its core objectives was to place the burden of proof on *industry*. Four decades ago, the predicted effects of TSCA for the manufacture and sale of chemicals was in fact seen as no less profound than REACH today – on paper at least. TSCA was the first American law targeted at the chemical industry as a whole. The 1972 introduction of a chemicals bill caused significant stir within an industry that at the time was relatively naive in the ways of Washington politics (Brickman, Jasanoff and Ilgen 1985: 242). Nonetheless, a coordinated assault against the bill deferred its enactment for four years. Ultimately unable to kill the bill in Congress, industry however succeeded in knocking out its regulatory fangs in congressional backrooms and subsequently during its administrative implementation (Bronstein and Wennerberg 1981; Collins 2010). As a result, and in sharp contrast to the act's initial intentions, elaborate statutory requirements, congressional oversight and judicial scrutiny today *de facto* places the entire burden of data collection and risk assessment on EPA and impedes the agency's capacity to intervene against even known carcinogens, such as asbestos.

Although REACH differs in important respects from TSCA – in part because its framers could draw on the record of TSCA's deficiencies – some of the key challenges to the statute's ability to achieve its objectives have yet to be encountered. REACH endows regulators with new authority to mandate data production and disclosure; but determining whether companies have provided complete responses remains as before a challenge. Initial compliance evaluation by the new European chemicals regulator, ECHA, for instance indicates that a significant proportion of registrations have shortcomings and need to be supplemented with additional information (ECHA 2011). It is also yet unclear whether the design of REACH can resolve the fierce disputes that will ensue when a lucrative and widely used chemical is shown to cause unacceptable risk (Abelkop *et al.* 2012: 11045). Authorization and restriction under REACH mandate some economic balancing of risks and benefits, and REACH will ultimately require the regulator to lift the burden of justifying that the benefits of restrictions outweigh their costs (Applegate 2008). Much of the information needed to quantify costs lies however exclusively within the particular knowledge of industry; and companies, which stand to benefit from delay or inaction, of course have no incentive to provide reliable estimates. In view of the U.S. experience, this turn to cost-benefit analysis in EU chemicals regulation thus in particular gives cause for concern. Manufacturers will in any event look to the risk assessment procedure and socio-economic analyses to defend their substances. John Applegate (2008: 746f.) observes: "the administrative process within the Commission […] for imposing restrictions (opinions of Risk Assessment and Socio-Economic Analysis committees must be solicited and responded to), and the review process with other organs, adopt a level of procedural complexity that in some ways rivals TSCA."

This overlap between the REACH restriction procedure and TSCA illustrates one of the perhaps inescapable dilemmas of toxic substance regulation. Chemicals legislation is by virtue of the arcane and obscure subject it seeks to regulate inherently complex. But complexity works in favor of those with the resources and knowledge to exploit it – that is, industry. On structure and process in politics, Matthew McCubbins and colleagues (1989: 469) write:

> "More elaborate procedures are generally regarded as favorable to regulated industries. Because industries possess much of the information relevant to regulatory decisions, elaborate processes give them more power by increasing the importance of that information. Another contributing factor is that industries, with greater economic stakes in regulatory issues, are more likely to devote the resources necessary to be effectively represented in expensive proceedings. In this case, established industries […] are more likely to be advantaged by cumbersome proceedings."

REACH runs close to 900 pages of dense legal text and regulations – a statutory complex which cannot fail but create wiggle room for enterprising corporate lawyers and legal experts.

Companies will at any rate and without fail scrutinize and probe every last page in search for legal loopholes and regulatory fissure that will allow them to keep their chemicals on the market.

Whether the procedures and safeguards in REACH will operate as intended or whether – as was the case for TSCA – they will be bent and subverted to serve the interests of manufacturers remains to be seen. As the 2018 implementation deadline draws near important issues still needs to be settled – the least of which is how REACH will regulate nanomaterials to ensure a sufficient supply of information on their potential human health and environmental effects (Azoulay 2012). Industry will of course mobilize to demand that their interpretation of scientific developments, technical feasibility and economic impacts are considered; and as before, the power to disclose, bias and withhold information will remain a significant source of influence over the decisions and outcomes of toxic substance control. Predictions that REACH will profoundly and inevitably transform the dynamics of chemical control policy are in short premature. Across the Atlantic, the momentum to update and strengthen TSCA meanwhile falters. Despite mounting frustration with the act's palpable shortcomings, pushback from the chemical industry and congressional gridlock combine to thwart attempts to reform U.S. chemicals legislation.

Must we then resign to leave decisions on the safety of chemicals in the hands of the very businesses that stand to gain from keeping them on the market? Of course not! The chemical industry is not omnipotent and manufacturers cannot do as they please. Industry is not the only source of information; and it certainly does not have a monopoly on expertise. Although perhaps disadvantaged in terms of resources, other groups also offer advice on chemical hazards. And while much information might be either under-supplied or inaccessible, state agencies do have their own sources of information and expertise. Governments routinely assess the harmful properties of chemicals and dangerous substances can be – and are – taken of the market, albeit perhaps not at the rate we would like. We can and should in short trust state authorities to protect our health and safety. But if we want regulators to prevent harm, we must of course also give them the budgetary means, regulatory tools and authority as well as independence required to implement their statutory obligations. If not, companies will face little resistance and few obstacles to their desire to keep dangerous substances on the market.

Manufacturers and users meanwhile do have cumulative experience from working with their chemicals as well as significant advantages in technical skills, access to data, and research capacity that cannot – and should not – simply be brushed aside. Because this information only to a limited degree can be secured through compulsion (Schneider 1985: 180), we must in other words also continue to look for methods to tap industry's superior knowledge, expertise and

resources. Companies for their part will – understandably – only volunteer information if they are confident that it will not be used to the detriment of their interests. The experience with nanotech regulation documented over the pages of this thesis suggests that one such method to encourage disclosure consists of establishing venues, where representatives from state authorities and industry can meet on a regular basis to debate potential sources of harm and their possible solutions. If such deliberative fora succeed in convincing companies that the decisions and outcomes of chemical safety policy will consider their inputs and – where possible – accommodate their interests, they might be instrumental to persuade companies to entrust regulators with sensitive information. Cooperation among regulators and industry thus remains as before a desirable feature of chemical control policy.

But it is not unproblematic either. Close and intimate relations among regulators and the industries they regulate undeniably risk the capture of state authorities. We must therefore demand and expect balanced participation in administrative risk management proceedings, lest advisory committees and stakeholder panels degenerate into vehicles of unchecked access and perhaps illicit influence. Bringing all relevant stakeholders to the table might facilitate mutual understandings of difficult-to-resolve scientific and technical problems, exchanges about the consequences of different decisions as well as afford participants opportunities to iron out their disagreements through discussion and negotiation. Regular deliberations among a closed group of experts might allow the parties to build trust and develop relations that facilitate candor in discussion – and companies may thus ultimately be more forthcoming and honest about sharing sensitive information. But just as likely however they will not. Our common interest in the safety of the chemicals we use and consume in any event demands that we find ways to convince companies to volunteer information about their substances. The alternative to recall the words of a German official is that 'otherwise industry would do the research and we would never see the data. Cooperation is also a way of controlling them.'[8]

[8] Interview, Berlin, June 22, 2012.

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APPENDIX A

List of Interviews

COUNTRY	LOCATION	DATE	AFFILIATION
Denmark	Phone	23 February 2011	Industry
Denmark	Copenhagen	9 March 2011	Government
Denmark	Copenhagen	9 March 2011	Industry
Denmark	Copenhagen	31 May 2011	Academia
Denmark	Copenhagen	1 June 2011	Industry
Denmark	Phone	2 July 2013	Government
Germany	Berlin	22 June 2012	Civil Society Organization
Germany	Berlin	22 June 2012	Government
Germany	Dessau-Roßlau	8 October 2012	Government
Germany	Dortmund	11 October 2012	Government
Germany	Frankfurt	11 October 2012	Industry
Germany	Phone	30 October 2012	Civil Society Organization
United Kingdom	Phone	1 March 2011	Civil Society Organization
United Kingdom	Brussels	2 March 2011	Industry
United Kingdom	London	3 March 2011	Government
United Kingdom	London	3 March 2011	Government
United Kingdom	London	3 March 2011	Academia
United Kingdom	Durham	6 June 2011	Industry
United Kingdom	London	7 June 2011	Civil Society Organization
United Kingdom	London	8 June 2011	Industry

COUNTRY	LOCATION	DATE	AFFILIATION
United States	Phone	3 April 2012	Academia
United States	Washington, D.C.	16 April 2012	Industry
United States	Washington, D.C.	17 April 2012	Civil Society Organization
United States	Washington, D.C.	18 April 2012	Industry
United States	Washington, D.C.	19 April 2012	Government
United States	Washington, D.C.	23 April 2012	Government
United States	Phone	31 May 2012	Industry